PB85-122653

Voluntary Standards-Setting for Drinking Water Chemicals Implementation Plan

National Research Council, Washington, DC

Prepared for

Environmental Protection Agency, Washington, DC

Oct 84

U.S. Department of Commerce
National Technical Information Service
NTIS

PB85-122653

VOLUNTARY STANDARDS-SETTING FOR DRINKING WATER CHEMICALS:

IMPLEMENTATION PLAN

Committee on Water Treatment Chemicals
Food and Nutrition Board
Commission on Life Sciences
National Research Council

National Academy of Sciences
Washington, D.C.
1984

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB85 122653
4. Title and Subtitle: VOLUNTARY STANDARDS-SETTING FOR DRINKING WATER CHEMICALS: IMPLEMENTATION PLAN			5. Report Date: 10/84
			6.
7. Author(s)			8. Performing Organization Rept. No.
9. Performing Organization Name and Address: National Research Council, Commission on Life Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418			10. Project/Task/Work Unit No.
			11. Contract(C) or Grant(G) No. (C) #68-01-6795 (G)
12. Sponsoring Organization Name and Address: U.S. Environmental Protection Agency			13. Type of Report & Period Covered: final
			14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

The report is advice and guidance to the Environmental Protection Agency (EPA) on a plan to allow the private sector to regulate drinking water additives. The report describes the roles and responsibilities of the third party, the testing organization and the EPA.

A decision flow chart (tree), decision points, and testing requirements are also included.

17. Document Analysis a. Descriptors

additive regulation
voluntary standards

b. Identifiers/Open-Ended Terms

indirect additives, water
drinking water

c. COSATI Field/Group

18. Availability Statement: "This report has been approved for public sale; its distribution is unlimited."	19. Security Class (This Report): unclassified	21. No. of Pages: Various
	20. Security Class (This Page)	22. Price

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The National Research Council was established by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and of advising the federal government. The Council operates in accordance with general policies determined by the Academy under the authority of its congressional charter of 1863, which establishes the Academy as a private, nonprofit, self-governing membership corporation. The Council has become the principal operating agency for both the National Academy of Sciences and the National Academy of Engineering in the conduct of their services to the government, the public, and the scientific and engineering communities. It is administered jointly by both Academies and the Institute of Medicine. The National Academy of Engineering and the Institute of Medicine were established in 1964 and 1970, respectively, under the charter of the National Academy of Sciences.

The work on which this publication is based was performed pursuant to Contract No. 68-01-6795 with the Environmental Protection Agency.

Copies available from

U.S. Department of Commerce
National Technical Information Service
Springfield, Virginia 22161

COMMITTEE ON WATER TREATMENT CHEMICALS

WILLIAM H. GLAZE (Chairman), University of California, Los Angeles, Los Angeles, California

ROY E. ALBERT, New York University Medical Center, New York, New York

ROBERT S. BRYANT, Stauffer Chemical Company, Westport, Connecticut

RICHARD A. FORD, Research Institute for Fragrance Materials, Englewood Cliffs, New Jersey

ARNOLD E. GREENBERG, East Bay Municipal Utility District, Oakland, California

RAYMOND D. LETTERMAN, Syracuse University, Syracuse, New York

JOHN H. MAHON (Retired), Calgon Corporation, Pittsburgh, Pennsylvania

CHARLES R. O'MELIA, Johns Hopkins University, Baltimore, Maryland

DAVID J. SCHAEFFER, Illinois Environmental Protection Agency, Springfield, Illinois

R. RHODES TRUSSELL, James M. Montgomery Consulting Engineers, Pasadena, California

Staff

ROBERT E. REHWOLDT, Food and Nutrition Board, National Research Council, Washington, D.C., Staff Officer

FOOD AND NUTRITION BOARD

KURT J. ISSELBACHER, Massachusetts General Hospital, Boston, Massachusetts, Chairman

RICHARD L. HALL, McCormick & Company, Hunt Valley, Maryland, Co-Vice Chairman

HAMISH N. MUNRO, Human Nutrition Research Center on Aging, Tufts University, Boston, Massachusetts, Co-Vice Chairman

WILLIAM E. CONNOR, Oregon Health Sciences University, Portland, Oregon

JOAN D. GUSSOW, Teacher's College, Columbia University, New York

PETER GREENWALD, National Cancer Institute, Bethesda, Maryland

RICHARD J. HAVEL, University of California School of Medicine, San Francisco, California

VICTOR HERBERT, Hahnemann University School of Medicine, Philadelphia, Pennsylvania

JAMES R. KIRK, Campbell Institute of Research and Technology, Camden, New Jersey

J. MICHAEL McGINNIS, Department of Health and Human Services, Washington, D.C.

REYNALDO MARTORELL, Food Research Institute, Stanford University, Stanford California

MALDEN C. NESHEIM, Cornell University, Ithaca, New York

ROBERT WASSERMAN, New York State College of Veterinary Medicine, Cornell University, Ithaca, New York

MYRON WINICK, Columbia University, New York, New York

SUSHMA PALMER, Executive Director, Food and Nutrition Board, National Research Council, Washington, D.C.

TABLE OF CONTENTS

	Page
EXECUTIVE SUMMARY	1
CHARGE TO COMMITTEE	1
SUMMARY AND CONCLUSIONS	1
CHAPTER 1 -- INTRODUCTION	3
CHAPTER 2 -- NONGOVERNMENTAL APPROACHES TO THE CONTROL OF HEALTH HAZARDS IN COMMERCIAL PRODUCTS	5
NONAGENCY REGULATION IN THE UNITED STATES	5
THE FEDERAL GOVERNMENT AND VOLUNTARY STANDARDS	7
STANDARDS RELATED TO HEALTH	7
STANDARDS AND THE DRINKING WATER TREATMENT INDUSTRY	8
American Water Works Association Standards	8
National Sanitation Foundation Standards Development	9
CERTIFICATION OF DRINKING WATER TREATMENT PRODUCTS IN THE NETHERLANDS	10
The Positive List	10
Toxicological Basis of the Positive List	10
The Toxicological Assessment by KIWA	12
Granting of the Toxicological Aspects Certificate	13
CHAPTER 3 -- THIRD PARTY CERTIFICATION OF DRINKING WATER TREATMENT ADDITIVES: ADVANTAGES, DISADVANTAGES, AND CRITERIA FOR ORGANIZATION	14
ADVANTAGES AND DISADVANTAGES OF THE THIRD PARTY APPROACH	14
Administrative Flexibility Associated with the Nonagency Approach	14
Public Trust and Industry Participation	15
Cost-Effectiveness of the Nonagency Approach	15
CRITERIA FOR SELECTION OF A THIRD PARTY PROCESS	16
Public Accountability	16
Independence	16
Expertise	17
Expedition of the Approval Process	17
Consistency and Fairness of the Process	17

	Page
CHAPTER 3 (continued)	
OPTIONS WITHIN THE THIRD PARTY APPROACH	18
RECOMMENDED OPTION	19
CHAPTER 4 -- THE THIRD PARTY APPROACH	27
RISK ASSESSMENT OF DRINKING WATER ADDITIVES	27
Hazard Assessment	28
Exposure Assessment	28
Dose-Response Assessment	30
Risk Characterization	30
Uncertainties in the Risk Assessment Process	30
STANDARD-SETTING AND CERTIFICATION	31
Standard-Setting	31
Certification Decision-Making	33
ROLES OF PARTIES WITHIN OPTIONS C AND B	36
Role of the Manufacturer	36
Role of the Testing Laboratory	36
Role of the Third Party	37
Role of the EPA or the Certification Board	37
Role of Advisory Bodies	38
OTHER DETAILS OF THE THIRD PARTY PLAN	38
CHAPTER 5 -- ANALYTICAL PROCEDURES EVALUATING DRINKING WATER TREATMENT ADDITIVES	41
MATERIALS TO BE TESTED	41
STANDARDIZED PROTOCOLS	41
TEST CONDITIONS	42
Test Conditions Related to Water Quality	42
Test Conditions Related to Physical Factors	43
Correlation of Test Conditions with Actual Use Conditions	43
ANALYSIS OF TEST EXTRACTS	44
Non-Specific Tests	44
Specific Tests	44
Bioassays or Toxicity Tests	45
Notes	50

Page

REFERENCES 51-52

APPENDICES:

A - Federal Register 1984

B - NSF Standard 14 for plastic pipe

Page

FIGURES:

Figure 2-1	Netherlands Toxicological Assessment Process	11
Figure 3-1	Option A. Role of Participants in Third Party Certification of Water Treatment Products (Non-Federalist -- Advice & Consultation)	21
Figure 3-2	Option B. Modification of Non-Federalist Option Shown in Figure 3-4 with Separation of Testing, Administration, and Approval Function (--Advice and Consultation)	22
Figure 3-3	Option C. EPA Certification of Water Treatment Products After Risk Assessment by Certification Board with Administrative Assistance from a Third Party	23
Figure 3-4	Option D. EPA Certification of Water Treatment Products with Third Party Acting as Testing Laboratory (--Advice and Consultation)	
Figure 4-1	Elements of Research, Risk Assessment and Risk Management of Water Treatment Additives and Materials of Construction	29
Figure 4-2	Standard-Setting Procedure for Water Treatment Additives	32
Figure 4-3	Flow Diagram for Product Certification Within Options B and C	34
Figure 5-1	Safety Decision Tree	47

TABLES:

Table 3-1	Roles of Participants in Four Options Involving Extra-Agency Involvement in the Certification of Water Treatment Products	25
Table 3-2	Advantages and Disadvantages of Third Party Options for Certification of Water Treatment Products	26
Table 5-1	Structure Category and Level of Concern (Exposure Risks)	48

EXECUTIVE SUMMARY

CHARGE TO COMMITTEE

In 1982, the U.S. Environmental Protection Agency (EPA) decided to transfer to a nongovernmental third party the oversight of chemicals used in the treatment, storage, or transmission of potable water. The agency included in this responsibility the evaluation of water treatment chemicals and the development of voluntary industry standards for their regulation.

The Committee on Water Treatment Chemicals of the Food and Nutrition Board was asked to assist the EPA in determining the type of third party plan that would be most appropriate for the task, and to describe in detail the overall framework of the plan, the decision-making process to be used, the types of data that would be needed, guidelines for selection of participants, and role of the various participants in the plan.

SUMMARY AND CONCLUSIONS

The committee reviewed various nongovernmental plans such as those developed by the American Water Works Association (AWWA), and the National Sanitation Foundation (NSF) for generating standards as well as decision flow charts (decision trees) currently in use both in the United States and in Europe. In addition, it considered the advantages and disadvantages of nongovernmental standard-setting, particularly in the certification of products that affect public health, safety, and the environment.

The committee concluded that if a consensus or voluntary standards approach is to be effective, five criteria need to be applied.

- public accountability
- independence
- expertise
- expedition
- consistency and fairness

In general, the majority of the committee were not convinced of the wisdom of the EPA withdrawing itself from the oversight of materials used in water treatment. Therefore, the development of a third party plan does not constitute an endorsement by the committee of a nongovernmental certification process for additives to drinking water.

Nonetheless, in view of its primary charge, the committee examined several organizational schemes for operating a third party certification program. These are presented in Chapter 3. Two of the schemes are considered in detail. Option C is the plan preferred by the committee and Option B is an acceptable alternative, should the EPA insist on completely removing itself from the process.

If a third party plan is adopted, the option recommended by the committee leaves with the EPA the final approval authority, but delegates to the third

party the following duties:

- administration of the process, including contact with manufacturers, processing applications, publication of standards, and maintenance of a modern data storage and retrieval system, and

- decision-making in routine cases within the specific and exclusive restraints of standards developed and approved by the EPA.

The recommended option does not allow the third party to act as a testing laboratory for the manufacturer's products. This duty would be delegated to EPA-approved external laboratories that must follow specific protocols and procedures outlined in the standards.

If the EPA excludes itself from direct participation, the committee prefers an alternative scheme (Option B) in which the third party continues to serve as outlined above, but final authority would be vested in an independent certification board, composed of experts appointed by an independent organization with national stature.

Chapter 4 describes the mechanisms of the two critical elements of the third party approach: standard-setting and certification. The procedure for developing a standard for a specific product involves the following key decision points:

- review of testing data submitted with product
- design of protocol for additional testing
- review of data
- recommendation to approve or withdraw from use

The roles of parties (EPA, testing laboratory, third party contractor, advisory or certification board) and the types of data needed at these points are included. Public participation in the setting of standards is important, and priorities for the different product types must be established. Certification is viewed as a largely routine duty of the third party, with the EPA (or the certification board, as the case may be) acting as final authority and appeal board for decisions, and as handler of special cases.

In Chapter 5, the committee discusses the development of protocols for testing products, including important considerations for extraction and analysis procedures. Current methods and procedures for obtaining and interpreting bioassay data are also presented. The committee does not recommend any specific protocol since the type and extent of testing will depend upon the product.

CHAPTER 1

INTRODUCTION

In 1958, the U.S. Public Health Service (PHS) began a system of advisory "approvals" on direct and indirect additives to water in response to interest displayed by state governments and a request by the American Water Works Association (AWWA). This advisory service was established in accordance with Sections 301 and 311 of the PHS Act (P.L. 58-703), which enabled the PHS to control the interstate transmission of communicable diseases (420.SC.264). Subsequently, it became the responsibility of the Environmental Protection Agency (EPA) to regulate the quality of drinking water as stipulated in the Safe Drinking Water Act (P.L. 93-523). However, the PHS Act did not authorize the regulation of chemicals in water.

Initially, these approvals were rendered by expert committees. However, after various reorganizations of the PHS and EPA, expert committees were replaced by an expert staff toxicologist within the PHS Bureau of Water Hygiene, which later became the Division of Water Supply and, eventually, the EPA Office of Drinking Water, which fulfills this responsibility today.

The EPA's advisory service has never considered all the products that might contribute chemicals to drinking water. For example, it never looked at such potential sources as chemicals frequently used in bulk quantities such as chlorine, lime, and alum, or materials used in piping and other products that come into contact with drinking water. Furthermore, the EPA advisory service was limited to the provision of advice; it was given no surveillance or enforcement powers. Consequently, it represented a severely limited effort to deal with the control of direct and indirect additives.

In 1979, the EPA Office of Drinking Water entered into a contract with the National Research Council (NRC) to produce a water chemicals codex comprising monographs describing individual direct additives to drinking water. The Water Chemicals Codex was prepared by the Committee on Water Treatment Chemicals (CWTC) and delivered to the agency in 1982.

In developing quality specifications to determine the purity of bulk chemicals, the committee considered all common contaminants in additives and specific impurities indicative of the various manufacturing processes. After reviewing all available information on the normal manufacturing practices involved in the production of additives and on the safety of the additives and their corresponding impurities, the committee formulated a set of specifications representing the minimum quality of additives suitable for use in the treatment and delivery of drinking water. Each monograph contains a physical and chemical description of the additive as well as recommendations for maximum allowable contamination limits. Other information, such as usual application rates and analytical methodology, is also included. The Codex, contains 36 monographs, and is used as a resource document -- not as a regulatory tool. Although some of its monographs pertain to bulk direct additives, the Codex does not include indirect additives, such as paints, coatings, and lubricants, or the complex formulations of coagulant aids.

In 1982, the EPA asked the Committee on Water Treatment Chemicals to develop a plan for evaluating water treatment chemicals through a third party. It stipulated that the plan should include a decision tree, giving a sequence of evaluation steps and a basis for determining the acceptability of an additive and its associated impurities in drinking water.

Chemicals that would fall within the third party's responsibility include polymeric coagulant aids, antiscalants and corrosion control agents, paints, and coatings, pipe materials, lubricants, membrane liners, well-drilling aids, and other miscellaneous products. Both existing products as well as new products would be considered.

The EPA identified seven specific tasks that the committee should perform:

- the development of standards, process, and plan, including detailed descriptions of the parties and the role of each;

- the development of a feasible approach for determining maximum allowable impurity concentrations and risk levels for both direct and indirect additives;

- the establishment of guidelines for assessing migratory characteristics and toxicological properties of ingredients in a given formulation;

- identification of analytical procedures and protocols for obtaining data;

- the establishment of a priority system for determining which products are examined first, including products that are currently in use;

- the development of plans for continuing periodic reevaluation and,

- the development of recommendations for adopting the system to respond to new concerns about drinking water additives as they emerge.

During the preparation of this report, the EPA published a notice of its intent to establish a private sector, voluntary standards organization or third party plan. The notice invited comments on this approach, and requested proposals from interested parties (see Appendix A).

CHAPTER 2

NONGOVERNMENTAL APPROACHES TO THE CONTROL OF HEALTH HAZARDS IN COMMERCIAL PRODUCTS

As noted in Chapter 1, the EPA decided in 1982 to investigate the possibility of transferring much of its drinking water additives program to the private sector. Hanson et al. (1983) explained the rationale for this decision and described the plan of action contained in a 1980 Memorandum of Understanding between the EPA and the FDA. In a recent issue of the Federal Register, the EPA (1984) elaborated on this plan and solicited proposals from nonprofit, nongovernmental organizations for assistance in developing and implementing a credible and efficient program in the private sector. It is clear from the Federal Register notice that EPA wishes to transfer the program to a so-called "third party". It is also clear that the agency recognizes its need to "maintain an active interest in the development of the program" and "to exercise its full authorities under the SDWA [Safe Drinking Water Act]" (EPA, 1984). According to Hanson et al. (1983), the EPA will reserve "the right of pre-empt activities of the third party...when the public health is threatened." However, it continues, "EPA will not play a decision-making role".

The EPA has also requested that the committee devise a plan for instituting the proposed nonagency approach. As such, this study may be viewed as an effort parallel to the intent of the Federal Register notice, which seeks input from the public on the EPA's proposed third party plan.

The key components of the advice solicited from this committee are listed in Chapter 1. As a prologue to succeeding sections, this chapter contains a discussion of the more general aspects of consensus or nongovernmental standard-setting as well as a review of nongovernmental approaches used in this country and abroad. The following section explores the advantages and disadvantages of the proposed third party plan and the criteria for selecting a third party approval system.

NONAGENCY REGULATION IN THE UNITED STATES

There are as many as 60,000 nongovernmental standards (Miyares, 1983) in the United States. These standards cover a variety of products and services in several major industries, including the metal, chemical, electrical, and nuclear industries. Compliance with the standards is voluntary, in the sense that no federal or state regulation requires it. In many cases, however, compliance is essential for marketing a product because of traditions in the industry and the marketplace. Nonconforming products, therefore, may be prevented from entering the market if they lack appropriate certification.

In a study of the broad issue of alternatives to governmental regulation, Baram et al. (1981) reviewed private self-regulation. They pointed out that standards developed by private industry fall into three major categories: standards created by a single firm for its products; industrial or professional standards created by industrial, trade, or professional associations for the practices, systems, and processes of raw materials used by its members, sometimes with the concurrence of suppliers or other interested parties, and consensus standards created by other organizations after persons with diverse interest have reached a consensus regarding the desirability and level of each proposed standard.

The investigators also discussed some of the pros and cons of self-regulation through the use of nongovernmental standards. The principal advantages attributed to such a system are cost-effectiveness, as compared to the alternative governmental approach, and more likely acceptance of the regulations by the industry being regulated. Potential disadvantages include failure to provide adequate safety levels, omission of input from the public sector, and denial to new business the opportunity to enter a market. Baram et al. (1981) concluded that the nongovernmental standards approach reflects strong industry self-interest and that any consideration of such standards as a potential regulatory device should be made with great care.

In a recent review of standards and certification by the U.S. Federal Trade Commission, Hamilton, (1978), described several safeguards that would help to instill public confidence in privately developed standards: the provision of reasonable notice to interested or affected persons or parties and an opportunity for them to participate in the developmental process; the development of standards through a consensus considerably greater than a majority of the development committee and the subsequently affected interests; the maintenance of adequate records; and the assurance that the public would be given access to the process.

Voluntary or consensus standards have been used in the preparation of government regulations for many years. In one method, a detailed statement of technical specifications is replaced in the text of the regulation by referring to one or more recognized standards.

Travaglini (1980) has reported that this method of referencing standards has been used by government agencies more frequently in the regulations concerning economics, such as the procurement of supplies, than in the regulations for public health and safety. As examples of standards-adoption processes, he has cited the Food and Drug Administration's (FDA) efforts in adopting international food product standards as U.S. standards, and the use of standards regulations of the Occupational Safety and Health Administration (OSHA) by the Consumer Product Safety Commission and the Department of Labor. Travaglini concluded that there are two important legal problems in referencing standards:

- the delegation of too much administrative authority to private standard-making bodies and,

- adherence to the due process procedures that must be lawfully observed in adopting standards.

The American Society for Testing and Materials (1975) has discussed the problems of the U.S. voluntary standards system. It concluded that some of the problems do not really apply to the voluntary standards system but, rather, are associated with the regulatory use of standards (referencing of standards). It identified the following problems as needing attention:

- the need for an improved coordinating force in the system;

- the lack of a single set of national standards;

- the need for a national policy on standardization by the U.S. Government; and,

- the need for a better understanding of consensus procedures, limitations of standards and transfer of standards from voluntary to mandatory use.

THE FEDERAL GOVERNMENT AND VOLUNTARY STANDARDS

The Office of Management and Budget (1982) issued a statement describing the federal government's role in interacting with voluntary standard-setting organizations.

The announcement provided policy and administrative guidance to federal agencies on the use of voluntary standards for procurement and regulation, on participation with private sector organizations to develop such standards, and on coordination of Executive Branch participation in the development of voluntary standards.

The notice encourages federal agencies to use voluntary standards whenever laws and regulations permit and to ensure that they will not adversely affect performance or cost, reduce competition, or have other significant disadvantages. In adopting and using voluntary standards, agencies are encouraged to give preference to standards based on performance criteria rather than on design, material, or construction criteria. It encourages knowledgeable agency employees to participate in the activities of voluntary standard-setting bodies and standard-development groups in order to preclude the need for development or maintenance of separate government standards.

STANDARDS RELATED TO HEALTH

It is generally recognized that standards related to health, safety, and the environment are difficult to formulate (Baram et al., 1981; Miyares, 1983). This is especially true when they concern exposures to weakly carcinogenic chemicals whose effects are difficult to measure. Risk assessment for such substances involves highly complex and sometimes controversial issues that, in general, the public has preferred to leave in the hands of government. In the United States, exposures to contaminants possibly associated with deleterious health effects are regulated through federal and state agencies under a series of statutes covering food, drugs, and cosmetics (administered by FDA); occupational environments (by OSHA); and, drinking water, air, pesticides, and other media (by EPA). The typical approach has been for Congress to authorize the appropriate agency to develop regulations with input from representatives of industry, the general public, and from scientific experts. This advisory process has taken on many forms, and different agencies have used the advice in different ways. In some cases, it is used merely to aid the agency staff in arriving at the final regulation. In other cases, however, the force of the advice from an expert panel or board is tantamount to adoption by the agency. For example, recommendations from the National Research Council's Food Chemicals Codex Committee are routinely adopted by the FDA as purity specifications for new

food additives. Other panels and boards used by government agencies include the EPA Science Advisory Board, FDA drug evaluation panels, EPA's Drinking Water Advisory Council, and various other panels of the National Research Council (e.g., NRC, 1983).

One panel of particular interest to this committee is the Flavor and Extract Manufacturers Association (FEMA) expert panel for review of flavor substances. This panel consists of experts in several areas, such as toxicology, pharmacology, and biochemistry, none of whom are associated with the flavor or food industry. Since 1960, this panel has advised the food industry and the FDA on the classification of flavor components into one of three categories: Generally Recognized as Safe (GRAS), Not GRAS, or Insufficient Evidence for Making a Decision. It is an independent, industry-funded activity. The panel's recommendations over the past 20 years have generally been adopted without revision by the FDA and by the flavor industry. Beginning in 1970, the FEMA expert panel collaborated with independent consultants to re-review more than 1,300 flavor materials.

It should be noted that the committee has found no evidence of critical analysis of nonagency certification programs, especially those which relate directly to human health. Whether these programs are more cost effective or in general, in the public interest, is largely conjectual at this time. A more thorough examination and analysis of such programs would seem to be in order before the concept of nonagency regulation is extended too far.

STANDARDS AND THE DRINKING WATER TREATMENT INDUSTRY

American Water Works Association Standards

In the drinking water treatment industry, standards have been developed by the American Water Works Association through committees of its members. These industry standards assist managers of community water systems and others who use chemicals and other supplies for water treatment by specifying minimum standards for assay, physical properties, and performance. Maximum contaminant levels of treatment chemicals are not presently covered by these standards.

The Standard for Aluminum Sulfate published by the American Water Works Association (1970) is a typical example of the type of standard used in the water supply industry for direct chemical additives. The aluminum sulfate standard has the following parts:

> Part A: General. This section gives the scope of the standard, a description of the material the purchaser should include in his specifications, and a statement concerning how the purchaser should notify the supplier if a shipment of material does not meet the requirements of the standard.
>
> Part B: Material. Part B defines "aluminum sulfate", covers the problem of contamination and health effects with a "no deleterious or injurious effects..." statement, gives the physical characteristics of the different types of aluminum sulfate, specifies what the active ingredient (Al) content should be.

Part C: Sampling, Inspection, Packing, and Marking. In this section, procedures are described for sampling the delivered product and methods for packing and shipping are given.

Part D: Testing Methods. Part D details how samples of the material should be handled prior to testing, and how to measure the active ingredient and contaminant concentrations.

National Sanitation Foundation Standards Development

Another organization concerned with consensus standards in the water industry is the National Sanitation Foundation (NSF). This independent, nonprofit organization develops voluntary standards and is involved in research, testing, and publishing in areas of public health and environmental quality. Manufacturers whose products, according to NSF testing and evaluation, meet a NSF standard are authorized to use the foundation's seal. When its standards do not cover a product type, the NSF, through its testing capability, provides a "certification service" in which a product is tested and evaluated to determine if a referenced standard or regulation is met. If the product meets the standard or regulation, the manufacturer is allowed to use the NSF "certified" mark and the product is listed in the NSF registry of certified products.

Most of its earliest work involved food equipment. In 1948, the NSF developed methods to establish uniform, nationally accepted, voluntary consensus sanitation standards. This effort resulted in the publication of approximately 50 standards and criteria related to food service equipment, water and wastewater treatment equipment, swimming pool water circulation equipment, radiation monitoring, health care equipment, and plumbing products for mobile homes and recreational vehicles.

Once the need for a standard has been established by consultations with affected parties (i.e., industry, government agencies, and consumers) or by discussions held at professional meetings, the NSF takes the necessary steps to begin the process of standard-setting through appointed committees. This usually involves two committees: a joint committee with overall jurisdiction during the development phase and a task committee to assist in writing the standard.

Membership on a joint committee is by invitation. All organizations involved select their own representatives. Representation from the manufacturers is broad and unrestricted in attendance. The NSF professional staff members coordinate the activity, provide secretarial services, and act as liaison between the joint committee and task committee composed of individuals knowledgeable about the product being evaluated. The chairman of the joint committee is selected from the current or past membership of the NSF Council of Public Health Consultants. Together, the joint committee and the task committee prepare a proposed standard. If additional laboratory testing is required, it is performed by the NSF.

After evaluating the draft standard, the joint committee may approve it and send it on to the NSF Council of Public Health Consultants, or it may

send it back to the task committee for reworking. If the joint committee rejects the draft, the entire subject is reworked by the task committee and resubmitted. The final decision concerning the official adoption of the standard is made by the NSF Board of Trustees after approval by the Council of Public Health Consultants.

CERTIFICATION OF DRINKING WATER TREATMENT PRODUCTS IN THE NETHERLANDS

The certification of water treatment products in The Netherlands is based on a "positive list" system which is implemented through a joint arrangement between a government Commission on the Health Aspects of Chemicals and Materials in Drinking Water Supply (CHCMD) and a private group called the Netherlands Waterworks Testing and Research Institute (KIWA). The CHCMD was established in 1976.

As shown in Figure 2-1, KIWA certifies a product on the basis of test data supplied by the manufacturer or obtained by KIWA. CHCMD evaluates toxicity data on substances found in water treatment products and uses these data to develop a list of acceptable compounds for inclusion in water treatment products.

The Positive List

The Positive List includes certain products that come into contact with drinking water, for example, plastic pipe, pipe coatings, and polyelectrolyte coagulants. The compounds on the list include monomers, additives, and impurities whose use is "toxicologically acceptable" in the manufacture of these products. Of the following three categories recognized by CHCMD, only materials in the first two (along with their maximum migration quantities, dosage limit or impurity content) are included in the Positive List:

- materials whose toxicities are so low that no limits need to be imposed for toxicological reasons;

- materials that, because of their toxicity, migration into drinking water, or their impurity content, require limits to be imposed;

- materials so toxic that their use in products coming into contact with drinking water is considered unacceptable for toxicological reasons.

The CHCMD develops a Positive List for each product or material type. The lists are available to the public so that manufacturers can use them in product development and water supply personnel will know what is considered toxicologically acceptable.

Toxicological Basis of the Positive List

Acceptable Daily Intakes (ADI) derived from standard animal experiments are the stated basis for toxicological assessment of materials that are candidates for inclusion on the list. The "no-toxic-effect level" for a given material and experimental animal is generally divided by 100 to give the "no-effect level" for human beings.

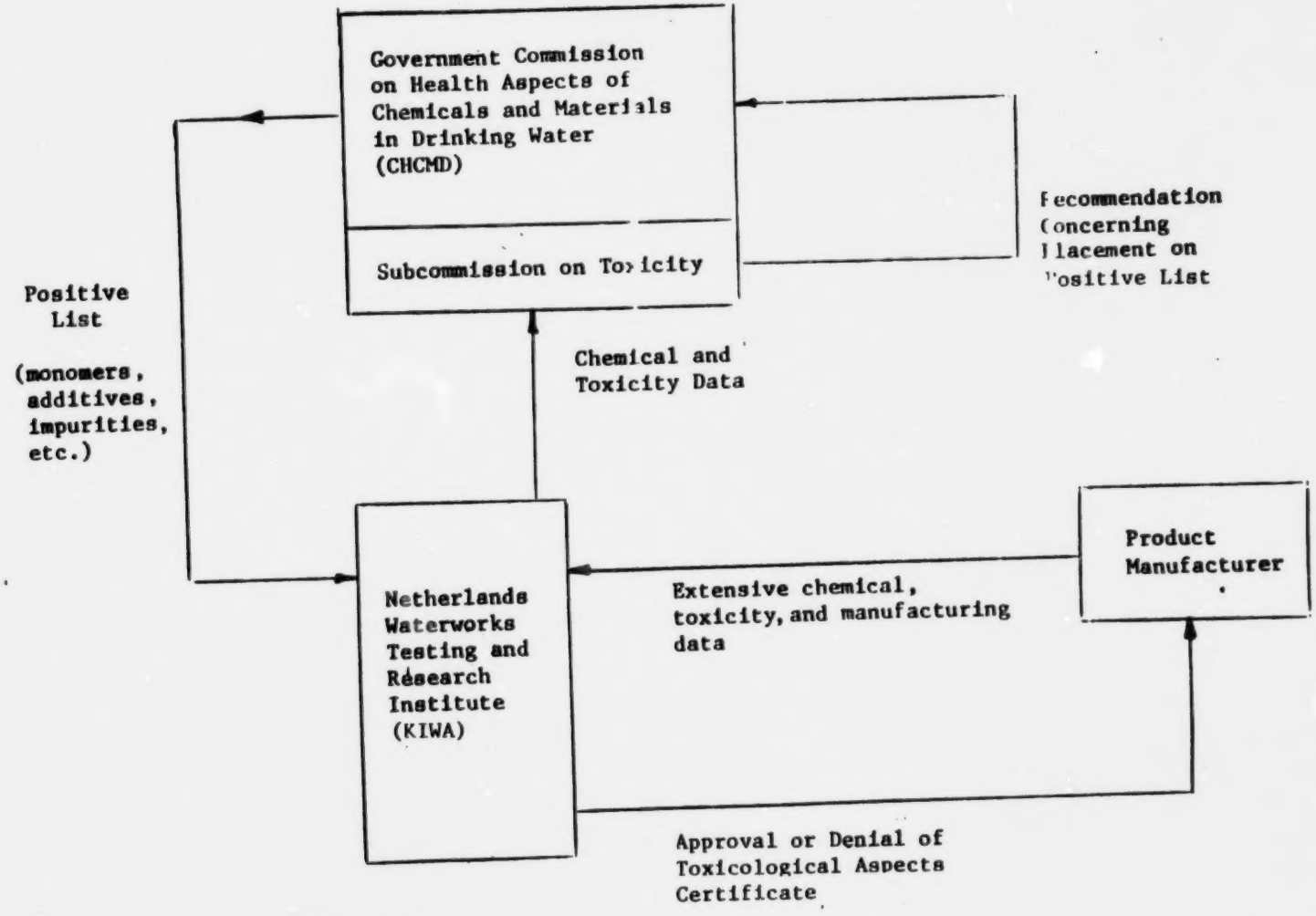

Government Commission on Health Aspects of Chemicals and Materials in Drinking Water (CHCMD)
Subcommission on Toxicity
Recommendation Concerning Placement on Positive List
Positive List
(monomers, additives, impurities, etc.)
Chemical and Toxicity Data
Product Manufacturer
Netherlands Waterworks Testing and Research Institute (KIWA)
Extensive chemical, toxicity, and manufacturing data
Approval or Denial of Toxicological Aspects Certificate

FIGURE 2-1
The Toxicity Assessment Procedure Practiced in The Netherlands

To account for multiple routes of intake, the CHCMD generally assumes that drinking water provides 10% of the intake of toxic substances by humans. It also assumes a daily water consumption of 2 liters in its calculations leading to the conclusion that an adult may consume 1/20th of the ADI per liter of drinking water.

The CHCMD also adheres to the following principles derived from the Dutch Food and Nutrition Council guidelines:

- the dose of a chemical used should be no higher than needed to obtain the desired effect,
- the chemical used should be as pure as possible, and
- the chemical used and the impurities in it should not lead to concentrations in drinking water that would be harmful to the consumer.

Toxicity assessment data are supplied by the manufacturer when a product is submitted to KIWA for evaluation. If a material is not on the Positive List, toxicological and chemical data are directed by KIWA to a CHCMD Subcommission on Toxicity, which analyzes the data and reports its recommendation to the CHCMD. CHCMD then determines whether or not the compound is to be included with appropriate limits, if any, on the Positive List.

The Toxicological Assessment by KIWA

KIWA requires each manufacturer to submit information that covers (as a minimum) the following points:

- trade name and field of application,
- complete chemical composition of the end product and raw materials,
- purity of end product and raw materials,
- description of the manufacturing process and specification of process chemicals,
- toxicity data, and
- analytical methods for controlling the composition of the product.

Forms supplied by KIWA are used to communicate this information. KIWA compares the product composition with the Positive List and decides which chemical analyses and, if necessary, simulation tests will be performed. Simulation tests are needed to determine if the product meets the migration limits given in the Positive List. The simulation tests are based on standardized procedures developed by KIWA. The chemical analyses are based on methods described in the Dutch Food and Utensils Law or by "best available method."

Granting of the Toxicological Aspects Certificate

After the product has been analyzed and simulation tests conducted, the results are compared with the requirements of the Positive List. If the product meets these requirements, KIWA grants a "Toxicological Aspect Certificate" (TAC). If the certificate is denied, the reasons are explained to the manufacturer.

CHAPTER 3

THIRD PARTY CERTIFICATION OF DRINKING WATER TREATMENT ADDITIVES: ADVANTAGES, DISADVANTAGES, AND CRITERIA FOR ORGANIZATION

In this chapter, the committee discusses some of the advantages and disadvantages of the third party approach for approving drinking water treatment additives, and provides criteria for selecting an organizational scheme for a third party approach. It also lists four options for the third party approach, including one which is recommended by the committee.

ADVANTAGES AND DISADVANTAGES OF THE THIRD PARTY APPROACH

Potential advantages of a third party (nonagency) approach, at least from the viewpoint of industry, to the approval of drinking water treatment additives include: reduced direct (tax-supported) costs for administration of the program, provided the program is paid for in part by user fees; more flexibility in administration; reduction of governmental bureaucracy; and more ready acceptance of standards by the affected industry. Potential disadvantages are the risk of diminution of public participation and control of the regulatory process; mistrust in some public sectors concerning industry-controlled regulatory activities that bear on public health; and difficulties associated with the interaction with existing agency-related regulatory efforts to maintain flow of information, consistency of approach, and coordination with current government policy.

Administrative Flexibility Associated with the Nonagency Approach

The committee is not convinced that the need for expeditious assessment of new products should be a compelling reason for adopting a nonagency regulatory approach. It is unlikely that a newly marketed product will be dramatically more effective for its stated purpose than the one already available. Moreover, the municipal water treatment industry is a relatively small user of most paints, coatings, and similar products. It is unlikely that a delay in making a new product available to the water treatment industry would have a significant impact on a manufacturer, even if a nonagency approach is not taken. Finally, it can be argued that rapid decision-making, particularly on cases involving complex risk assessments, could be detrimental to the interests of the general public.

However, one characteristic of the nonagency approach is the possibility of rapid consideration of new products to be certified for water treatment applications, for example, new paints and coatings and new polymeric additives. Materials in these categories are changing in composition yearly, and new products will have to be reviewed often if they are to enter the water treatment market. Moreover, some 2,300 products now on the market that have not been approved will have to be assessed in the initial stages of the program.

Given the complexity of the Federal Government's administration of environmental regulations, it seems safe to assume that a third party

could administer the water treatment additives program more expeditiously than the EPA alone. Expedition is used in this context principally to mean in a more timely manner, as perceived by the industry that is regulated. In the final analysis, this may also mean that the program is more effective.

Another concern is the correlation of third party activities with those of other governmental bodies. Ultimately, the regulation of water treatment chemicals and construction materials must be justified by its ability to minimize detrimental human health effects. Increasingly today, in environmental and occupational areas, this means minimizing the risks of cancer and forms of genotoxicity. Information on carcinogenic substances is constantly unfolding as are developments in the field of cancer risk assessment.

Public Trust and Industry Participation

Federal regulation of the municipal water treatment industry is a relatively new activity, having begun formally with the 1974 Safe Drinking Water Act. The passage of this act coincided with increased public awareness of sources of environmental contamination and their associated risks to human health. Recent polls suggest that public concern in this area has not abated significantly and that there will be constant pressure on the Federal Government to protect public interests. Therefore, a third party plan would be effective only if the public sector believed that its interests would still be protected under this approach. On the other hand, the U.S. water works industry has generally taken a responsible approach to protecting public health, even in the absence of federal regulations. The imposition of the Safe Drinking Water Act was not received with hostility by the industry, although the industry as a whole probably does not see the need for federal regulation of water treatment additives. Thus, a voluntary third party approach to standard-setting would be most palatable to the industry and most likely to receive industry cooperation. It would, however, be subject to criticism from public interest and consumer groups. The effectiveness of the voluntary third party approach then will depend on assurances to the public and to the industry that the program is based on credible science and is administered fairly.

Cost-Effectiveness of the Nonagency Approach

Given the many uncertainties of the proposed third party approach, the committee is unable to judge its cost effectiveness. A voluntary approach supported by user fee would probably be less expensive for the taxpayer. The user fee however, would be dependent upon the degree of product test data needed and the protocols needed to gather the data. The EPA most likely will continue to maintain some involvement in order to assist and monitor the nonagency system (Hanson et al. 1983).

Moreover, there are other potential costs to the public that must be weighed in evaluating the third party approach. First, user fees charged to manufacturers by the third party will eventually be passed on to consumers. Second, as in all matters of public health control, there are costs associated with health care facilities and services. For these costs to be equivalent in the agency and nonagency approaches, the net protection to public health must be the same in both systems. The assurance that this will be the case implies again some form of federal role with attendant costs. Thus, it is not clear that the net savings to be gained from a nonagency approach are as sizeable as one might assume upon first consideration.

CRITERIA FOR SELECTION OF A THIRD PARTY PROCESS

Five criteria appear to be essential in any regulatory program that involves the protection of public health:

- public accountability;
- independence of the approval body from the affected industry;
- an appropriate level of expertise in the groups doing the testing, risk assessment, and approval;
- expedition of the approval process; and
- consistency and fairness.

Public Accountability

This is a singularly important feature of all regulatory programs designed to protect public health. As noted in the previous section, and acknowledged in the EPA's most recent announcement in the Federal Register (EPA, 1984), public access and contributions to the approval proceedings is essential in programs of this type. Moreover, the third party must eventually be held accountable to the general public with regard to its decisions in specific approval cases. A mechanism to ensure accountability of the third party should be an essential component of a nonagency approval process.

The committee also recommends that the third party provide a mechanism for public comment during the evaluation. Examples of mechanisms used in other processes that invite public comment are:

- public notice with invitation to submit written comments;
- public meetings; and
- public liaison panels.

Independence

Regardless of whether the approval of water treatment products is voluntary or mandatory, the protection of public health requires that the process be independently administered. This means that the groups testing and approving the product should have no connection, either direct or indirect, with the industry being regulated. If the approval is the responsibility of a third party, rather than the EPA, then that party must adhere to the same standards in protecting public health as a public agency.

Standard-setting and approval should not be the responsibility of the same agency (NRC, 1983). Therefore, testing, and risk assessment for final approval decisions should be done by independent groups.

Independence does not imply a lack of communication between the parties involved. Indeed, communication is necessary to expedite the process. Moreover, testing must be conducted in accordance with procedures and needs

expressly approved by the central approval agency, and information about these procedures must be shared by all parties.

Expertise

Groups involved in the evaluation and certification process should have special types of expertise. Testing (e.g., extraction, analysis, and bioassays) should be conducted by appropriately skilled personnel and data should be evaluated by experts in risk assessment procedures. Those involved in the final approval process must have exceptional insight and appreciation of the entire process.

Expedition of the Approval Process

The approval process should be completed as rapidly as possible, preferably within a few months from the date of submission. However, the compilation of testing data, especially complete bioassay data, will be a lengthy process. Thus, the times required for approval will range from a few weeks for a nontoxic product to perhaps years for more complex cases.

Consistency and Fairness of the Process

The approval process should be fair and consistent. It must be free of bias and must utilize procedures that are open, well managed, and based on good science. Throughout the entire process, quality assurance procedures should be consistently and rigorously applied. This is especially critical for the acceptance of testing data, including extraction, analyses, and bioassay results. Procedures used should be consistent, if possible, not only within the third party organization but also with procedures used in other federal agencies.

Fairness of the process also implies that the risk management process will take into account the potential benefits as well as the risks that may result from approval. For water treatment products, a benefit of a new product is often the fulfillment of a function at a lower cost, improved efficiency at higher costs, or the provision of a technical effect not offered by any available product. These factors must be considered in the overall risk management process.

Fairness also requires that the confidentiality of a manufacturer's proprietary data be maintained. This is one of the most serious and demanding requirements of any product approval process in a capitalistic society. It represents a significant challenge to any third party in that the ultimate success of voluntary compliance rests on the willingness of the industry to submit its products to the approval agency. The third party plan must provide assurances to the industry in this vital area.

The requirement for consistency has another aspect not explicitly acknowledged by the EPA in its Federal Register notice; namely, the need for the approval process to be continued into the indefinite future. Will a third party charged with approving water treatment products be responsible in perpetuity, or will it be necessary (for whatever reasons) to choose another third party some time in the future? If the latter, there may be difficult problems in the transfer of information and maintenance of confidentiality.

OPTIONS WITHIN THE THIRD PARTY APPROACH

Four principal parties are involved in the certification process: the manufacturer or purveyor of the product; the testing laboratory; the third party, or the group selected by the EPA to serve as administrator of the certification program; external board and the public sector, represented by the EPA, state agencies, and expert committees.

The committee considered several possible organizational schemes by which the EPA and the third party could fulfill the required responsibility of the additives program, keeping in mind the criteria discussed in the previous section. Four such schemes emerged, ranging from one in which the third party assumes essentially complete control of the program to one in which the EPA uses the third party essentially as a contractor to aid the federal agency in testing the products and processing the applications but not in decision-making. Intermediate between these two extremes, there emerged two options in which the federal agency delegates its decision-making authority but only within the context of specific guidelines (standards) that must be followed explicitly by the third party. The difference between the two intermediate schemes lies in the standard-setting process. In one, the EPA assumes the responsibility for standard-setting; in the other, standards are set by an independent board of experts. Advice or procedures to establish such a board should be sought from an independent body. These four options are discussed in the following paragraphs.

Option A. The least federalistic option, shown in Figure 3-1, is referred to as Option A. In this option, the EPA would essentially be eliminated from the approval process except as an advisor in standard-setting or as a preemptor in the extraordinary case where public health is judged to be threatened. The third party would develop standards for each category of product, receive the application from a manufacturer or purveyor, assemble and evaluate product test data according to procedures specified in the standard, and approve or disapprove the product. It could seek advice from the EPA or other experts as it wished. This option would probably be the most expeditious of the schemes considered and the least expensive in terms of federal outlays required. It would also probably be the most acceptable to most industries. Its disadvantages are that it removes the decision-making process from the public sector and it may not conform to the criteria for independence or public accountability.

Option B. This would overcome the disadvantages of Option A while retaining the private sector approach. The third party would be the administrator of the program and would make most of the certification decisions, but only within the context of very specific guidelines. The decisions would be approved by a certification board composed of independent experts in water chemicals and health disciplines. This board would also have ultimate authority for the approval process and could preempt the decision-making role of the third party in extraordinary cases. The third party would still make most of the approval decisions falling within the evaluation protocols. However, to keep the testing and approval processes independent of one another, it is recommended that the third party should not

conduct testing for manufacturers. Rather, in conjunction with the certification board, the third party should approve other laboratory organizations for testing of products. The advantages of this are its placement of ultimate authority in the hands of an independent expert panel and its separation of testing and the evaluation of those tests (i.e., certification). Its disadvantages are that it could result in delays and communication problems, and it will require safeguards to ensure confidentiality of manufacturers' data. This option also requires that the third party establish a mechanism for public accountability and comment.

Option C. This is similar to Option B except that the certification board's function is to make recommendations to the EPA but final decision-making authority is retained by the EPA. But as in Option B, the third party is authorized to make routine certification decisions within the specific constraints of standards set by the EPA. Its advantage is that it leaves in the hands of a public agency the responsibility for making decisions that may affect public health while placing the bulk of operational responsibility in the private sector. Since the EPA is the final decision-making authority in this process, the mechanism for public accountability and comment already exists. Its disadvantages are the same as those of Option B but, in addition, would require an even larger EPA staff.

Option C also introduces the concept of an advisory body or board. The purpose of the board is to review procedures and protocols used by the third party and testing laboratory and to advise them and the EPA as to the appropriateness of the choices.

Option D. Option D is the antithesis of Option A in that it makes the certification program a federal program and omits the third party from the approval process. Essentially, the third party would act within this option as a contractor to EPA, much as the federal government uses external contractors at some of its regional laboratories. The third party would act as staff to process applications and to refer them to the EPA for decision-making. In addition, since the third party is removed from the decision-making process, it could also carry out testing for manufacturers within the guidelines of the appropriate standard. This program would keep decision-making entirely in the public sector, and it allows for testing and application processing by the same agent, i.e., the third party. However, it would require the largest federal staff of all of the options, and it would probably be the least expeditious. An advisory board could also be used in this option. Option D is outlined in Figure 3-4.

Table 3-1 summarizes the roles of the various participants in the four options discussed above. Table 3-2 lists some of the advantages and disadvantages of each option.

RECOMMENDED OPTION

Should a third party approach be adopted for the certification of water treatment products, a management scheme should be utilized which will ensure public accountability in the process. It is the committee's position that this be accomplished by the EPA maintaining an active role in the process, with final decision-making authority vested in the third party. A private organization operating in a closed system cannot exercise this authority as independently as a government agency or an external board of experts. In

addition, an appropriate level of public participation must be built into the process if it is controlled by the private sector. These concerns will become more evident as controversial issues arise, e.g., when risk assessments must be interpreted, when there are choices between bioassays, and when risk-benefit ratios must be evaluated. Although most water treatment products may be handled in a routine, noncontroversial manner, the system must ensure that the general public will be properly represented, especially in controversial cases. The EPA (1984b) has recognized this potential deficiency in the third party approach in its recent Federal Register notice by requesting comments on its statement that "more formalized regulation and control of additives better protect the public health?" (1984).

Of the four options shown in Figures 3-1 to 3-4, and in Tables 3-1 and 3-2, the committee favors Option C (Figure 3-6) in which the EPA retains the final authority for approval of products but delegates a substantial amount of the work to a third party and a testing laboratory. This arrangement would not necessitate a sizeable number of EPA personnel if the agency's role is largely limited to oversight.

Should the EPA insist on removing itself entirely from the certification process, an alternative the committee does not recommend, the committee would prefer a third party organization similar to Option B. In this option, final decision-making authority is vested in an independent board of experts, termed the certification board. The criteria for an acceptable voluntary standards process can still be met in Option B if:

- care is taken to assure public participation at the early stages of the preparation of the recommendations for new standards;
- an advisory body, assures adequateness of procedures and overall fairness of the process; and
- an independent body maintains final decision-making authority.

Finally, since it calls for most of the labor intensive steps; testing, process administration and management to be done outside of the EPA, it is projected to reduce the staff and financial involvement of the agency.

Should this option be adopted, it is recommended that the certification board consist of approximately nine (9) recognized experts, in the fields of toxicology, analytical chemistry, biostatistics, and environmental engineering. The members of the board should be drawn from academia (five); the water treatment industry (one); manufacturers of water treatment products (one); the EPA (one); and the NIH (one). Establishment of criteria for membership on the board, procedures to ensure adequate representation of all concerned parties and mechanisms to periodically modify membership should not be the responsibility of the third party. The committee recommends that an independent external organization of national stature be consulted for recommendations on establishing a certification board.

Further details on the mechanics of the certification process and the preferred options are discussed in the following chapter.

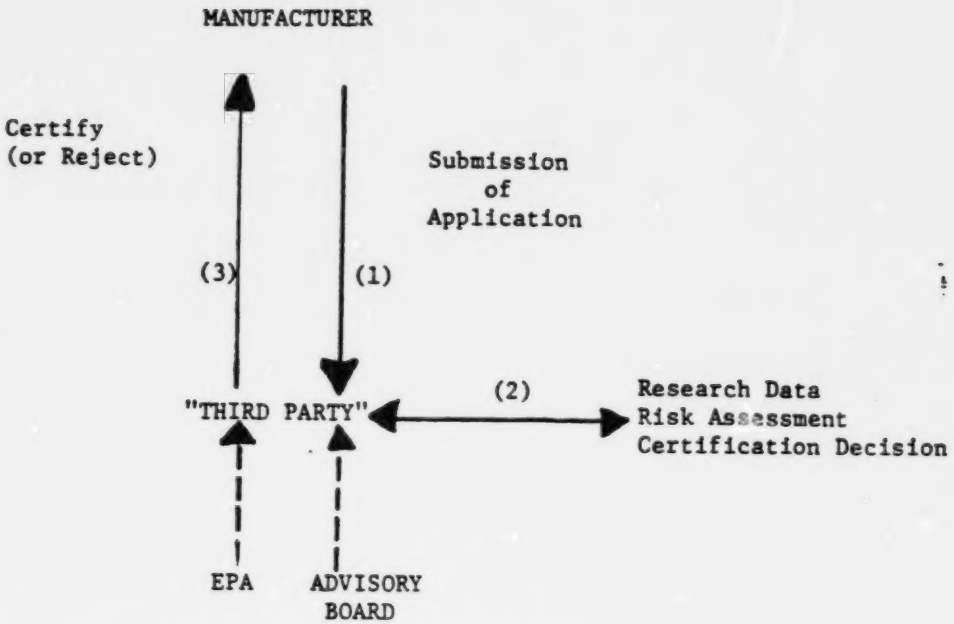


FIGURE 3-1

Option A. Role of Participants in the Third Party Certification of Water Treatment Products (Non-federalist -- Advice & Consultation) (Numbers refer to process sequence).

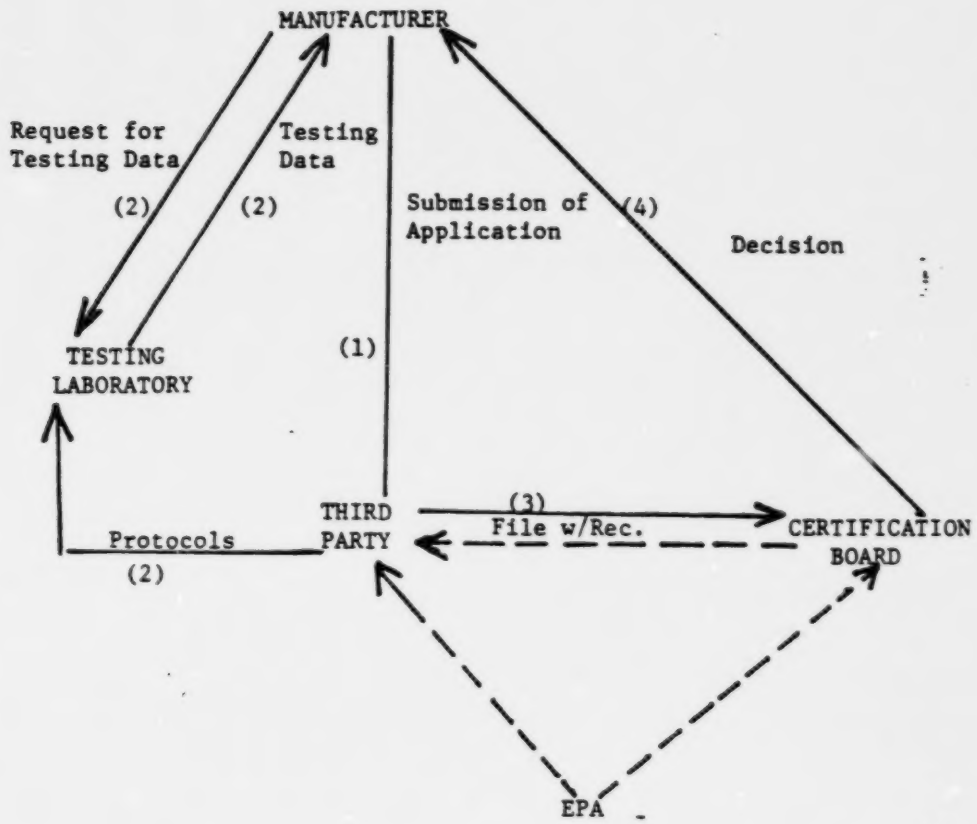


FIGURE 3-2

Option B. Modification of Non-federalist Option Shown in Figure 3-4 with Separation of Testing, Administration, and Approval Function (-----Advice and Consultation). (Numbers refer to process sequence)

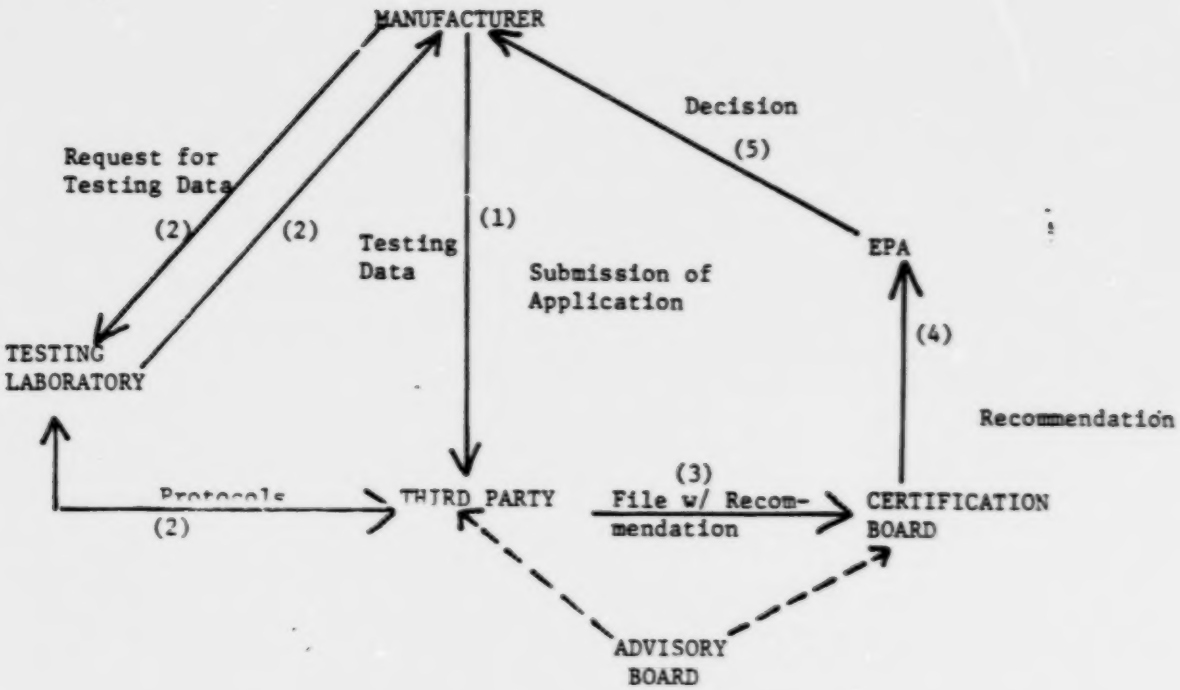


FIGURE 3-3

Option C. EPA Certification of Water Treatment Products After Risk Assessment by Certification Board with Administrative Assistance from a Third Party. (Numbers refer to process sequence)

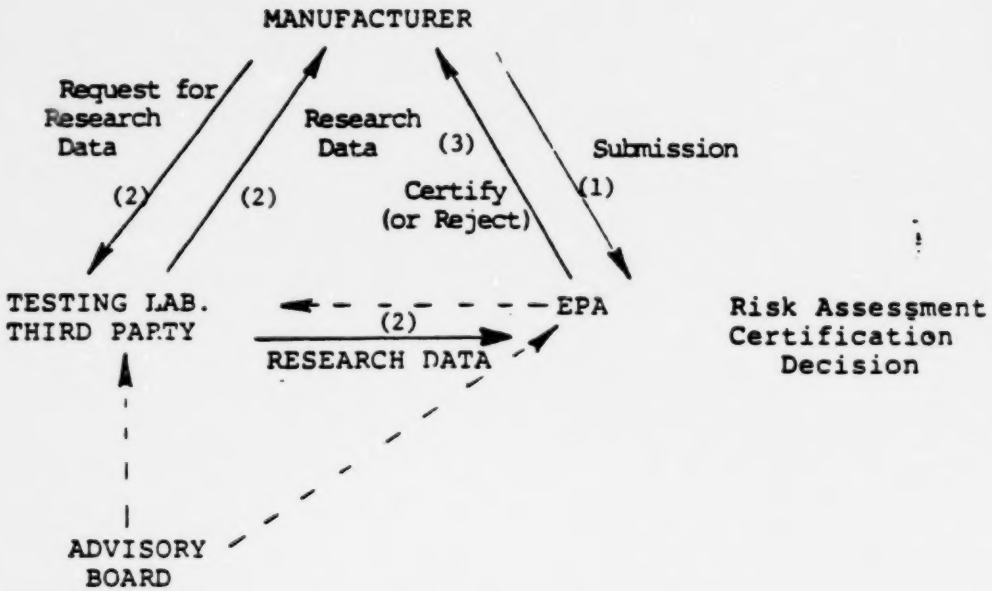


FIGURE 3-4

Option D. EPA Certification of Water Treatment Products with Third Party Acting as Testing Laboratory (-- Advice and Consultation)

TABLE 3-2

ADVANTAGES AND DISADVANTAGES OF THIRD PARTY OPTIONS FOR CERTIFICATION OF WATER TREATMENT PRODUCTS

OPTION	ADVANTAGES	DISADVANTAGES
A	Minimizes size of EPA staff required for certification; expeditious decision making; ready acceptance by industry.	Decision-making removed from general public; possibility of decisions in risk assessment inconsistent with other federal agencies; testing and evaluation by same body.
B	Minimizes size of EPA staff; decision-making by independent expert panel; ready acceptance by industry; separates testing and evaluation by same body.	Decision-making removed from general public; decisions in risk assessment may be inconsistent with other federal agencies; less expeditious than Option A.
C	Decision-making more accountable to general public; testing independent of risk assessment process; decisions more consistent with other federal agencies; EPA staff requirements less than in Option D.	Larger EPA staff required than in Options A or B; decision-making less expeditious; less acceptable to industry.
D	Decision-making directly accountable to general public; testing independent of risk assessment process; decisions more consistent with other federal agencies.	Largest EPA staff required of all Options; decision-making less expeditious; least acceptable to industry.

TABLE 3-1

ROLES OF PARTICIPANTS IN FOUR OPTIONS INVOLVING EXTRAAGENCY INVOLVEMENT IN THE CERTIFICATION OF WATER TREATMENT PRODUCTS

OPTION	MANUFACTURER	TESTING LABORATORY	THIRD PARTY	EXTERNAL BOARD	EPA
A	Contracts with third party Submits application to third party	Provides extraction/ analysis and bio-assay data to manufacturer	Develops standard Receives application Reviews for completeness Conducts tests as needed Makes approval decision	Advisory: Advises third party on standard development	Advises third party on standard development Emergency action to protect public health
B	Contracts with testing laboratory for tests Submits application to third party	Provides extraction/ analysis and bio-assay data to manufacturer	Receives application Reviews for completeness Makes approval decision according to approved standard Prepares dossier for new standard	Certification: Reviews dossier on standard development presented by third party Approves new standards Advises third party on protocols and procedures	Advises third party and certification board Emergency action to protect public health
C	Contracts with testing laboratory (or third party) for Tests	Provides extraction/ analysis and bio-assay data to manufacturer (May be third party)	Receives application Reviews for completeness Prepares dossier for new standard	Advisory: Advises third party and EPA on protocols and procedures	Receives dossier on standard development from third party Approves new standards Advises third party on protocols and procedures
D	Contracts with testing laboratory Submits application to EPA	Provides extraction/ analysis and bio-assay data ← →	Provides extraction/ analysis and bio-assay data	Advisory: Advises EPA on procedures and protocols	Develops standards Receives application Reviews for completeness Makes approval decisions

CHAPTER 4

THE THIRD PARTY APPROACH

More than 2,000 chemicals or formulations are used in the drinking water industry. In addition, many new water treatment chemicals are being introduced each year. Because the EPA does not have statutory authority to regulate drinking water chemicals, these chemicals and formulations have never been subjected to rigorous evaluation. The implication of this is quite clear. The third party certification process must include an initial screening procedure to determine a priority order for evaluating chemicals and formulations now in use.

The Food and Drug Administration, faced with a similar problem in its periodic reevaluation of food chemicals, has outlined a method to assist in making priority decisions (FDA, 1982). Although the evaluation of food chemicals is made complex by the great variety of food categories, use levels, and intakes, a similar system would be applicable to water treatment chemicals.

There are two essential aspects to the third party certification process: the development of criteria and protocols for decision-making and the application of these criteria in the evaluation of various products. The former is often called standard-setting, and it is here that experts are required to ensure that the technical basis of the standards is sound. After the standards and procedures are codified, they may be applied in a more or less routine fashion by less qualified personnel. Given the large number of products to be evaluated, it is essential to allow much of the routine work to be done by the party that will administer the program, i.e., the third party. However, the mechanism should reserve for the EPA or an independent, external board, the ultimate decision-making authority.

The following sections contain discussions of risk assessment as well as standard-setting and certification within the two preferred third party options (Option B and C) defined in Chapter 3.

RISK ASSESSMENT OF DRINKING WATER ADDITIVES

The objective of the certification process is to determine if a given product is likely to contribute contaminants to treated water and, if so, what risk to human health is associated with these contaminants. The process for making these determinations is risk assessment directed toward the making of decisions (risk management) and, in this case, whether to certify a given product for marketing to the water treatment industry.

In its broadest sense, risk assessment should answer two questions -- one qualitative and the other quantitative:

- How likely is an agent in the product to be toxic to humans?
- What is the degree of toxicological impact on an exposed human population, given the estimated levels of exposure?

The qualitative aspect has been termed hazard assessment, and the quantitative aspect includes dose-response, exposure assessment, and risk characterization. Figure 4-1 is a modification of a figure contained in a recent risk assessment report describing the elements of risk assessment (NRC, 1983).

Hazard Assessment

In the context of this report, hazard assessment is the determination of the likelihood that a product is likely to contain contaminants that may be causally linked to human health effects. As noted above, hazard assessment (or hazard identification) is a qualitative process signalling that a product may require further testing or evaluation before being allowed on the market. Hazard assessment is aided by a thorough knowledge of a product's composition, the manufacturing and processing methods used, and likely constituents in the product, including by-products and raw materials.

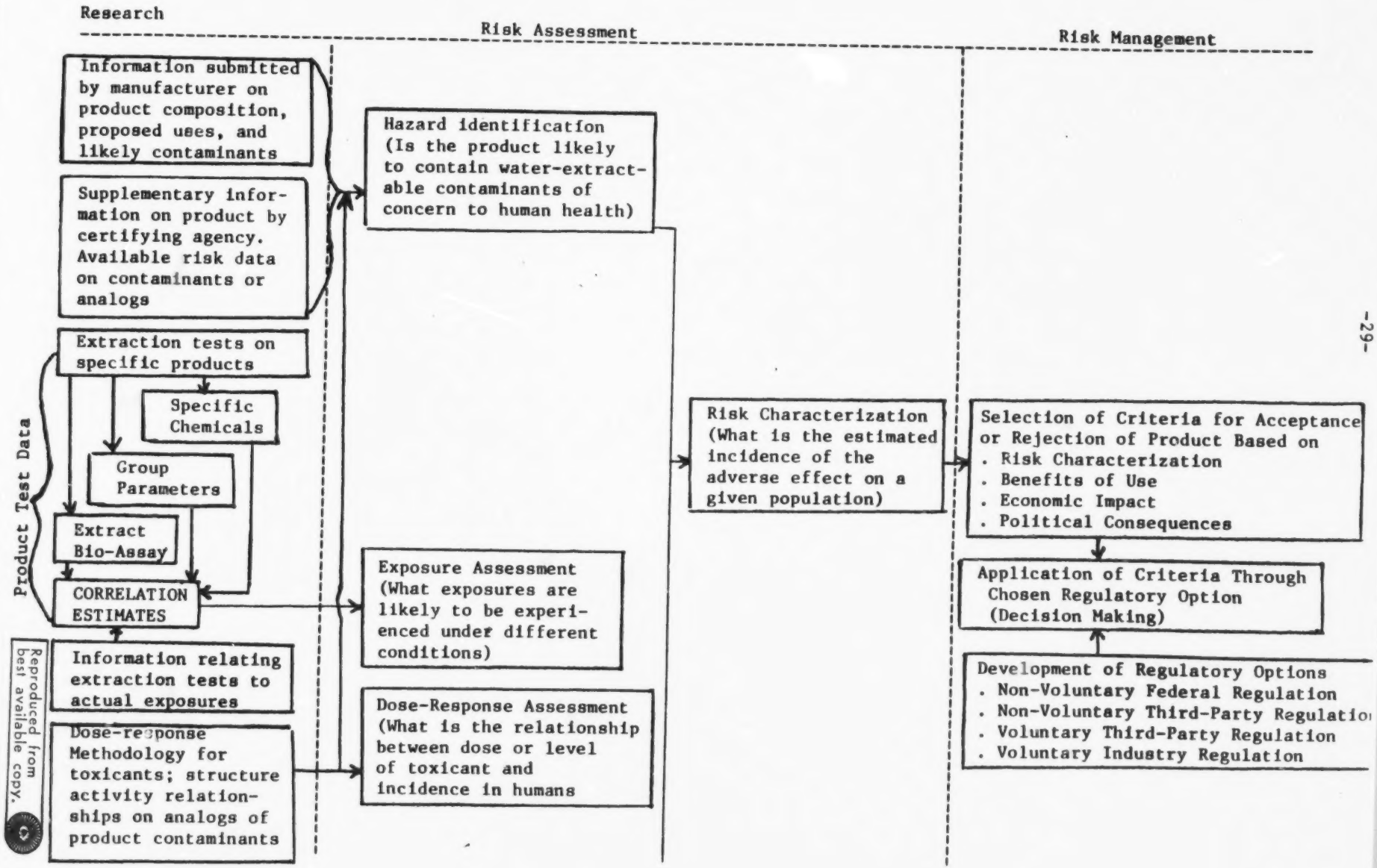
Exposure Assessment

This activity involves the determination of exposures likely to be experienced by humans who consume water that has been in contact with the product. The experimental data for this assessment are the results of the product tests. Since this subject is discussed in more detail in Chapter 5, only the important elements are presented here.

Product tests are devised to determine if a given product will release to water any contaminant that may adversely affect health. Two experimental questions are of interest: what contaminants are released, and at what level are they to be expected in the finished drinking water? Thus, experimental protocols must be developed for each category of product and precisely used to evaluate each product. For direct additives, such as polymeric coagulants, the product may be added directly to a test water under a specified set of conditions (e.g., pH, temperature, time, additive dose, and chlorine residual). The water may then be filtered, yielding a test extract that may be analyzed for specific contaminants. Similarly, materials used to construct components of a water treatment system (e.g., pipe, coating, or gasket) may be subjected to either a static or dynamic test to determine if contaminants are leached from them into the water. In each case, it will be necessary to make correlation estimates to relate the product test results to actual use conditions in order to estimate an exposure level for persons who consume the water.

Within the regulatory community, there is also interest in the use of nonspecific tests and bioassays instead of, or in addition to, specific contaminant tests. Nonspecific tests, such as total residue obtained from an extract, are discussed in more detail in Chapter 5. In principle, they may be utilized in the same fashion as specific compound data in the risk characterization process. However, because nonspecific determinations do not often have firmly established relationships with health effects in humans,

FIGURE 4-1 Elements of Research, Risk Assessment and Risk Management of Water Treatment Additives and Materials of Construction


Research
Risk Assessment
Risk Management
Information submitted by manufacturer on product composition, proposed uses, and likely contaminants
Supplementary information on product by certifying agency. Available risk data on contaminants or analogs
Hazard identification (Is the product likely to contain water-extractable contaminants of concern to human health)
Extraction tests on specific products
Specific Chemicals
Group Parameters
Extract Bio-Assay
CORRELATION ESTIMATES
Product Test Data
Information relating extraction tests to actual exposures
Dose-response Methodology for toxicants; structure activity relationships on analogs of product contaminants
Exposure Assessment (What exposures are likely to be experienced under different conditions)
Dose-Response Assessment (What is the relationship between dose or level of toxicant and incidence in humans
Risk Characterization (What is the estimated incidence of the adverse effect on a given population)
Selection of Criteria for Acceptance or Rejection of Product Based on
. Risk Characterization
. Benefits of Use
. Economic Impact
. Political Consequences
Application of Criteria Through Chosen Regulatory Option (Decision Making)
Development of Regulatory Options
. Non-Voluntary Federal Regulation
. Non-Voluntary Third-Party Regulatio
. Voluntary Third-Party Regulation
. Voluntary Industry Regulation

Reproduced from best available copy.

they are probably of most use as screening tests in standards development. Values obtained could be used to determine whether a bioassay tier is required. However, even this approach may be criticized, given the fact that the total weight of the residue may not be proportional to toxicity of the residue. Therefore, further study of nonspecific determinations is needed before they can be adopted for the present use with confidence.

Dose-Response Assessment

In the classical application of risk assessment and management, dose-response data obtained from animal feeding studies are used in conjunction with exposure as data components of the risk characterization step. Dose-response assessments for specific compounds are based on well-characterized principles and procedures (NRC, 1983). It is possible, and indeed highly probable, that contaminants known to be present in a given product will not have been thoroughly tested for toxic properties. In this case, it may be necessary to conduct more toxicological tests on the contaminant before a complete risk assessment is possible. However, it is neither practical nor possible to conduct a comprehensive battery of toxicological tests on all potentially deleterious materials. To do so would be prohibitively expensive and time consuming. It remains, therefore, for decision-makers to determine which data are necessary for judgment of safety to be made with reasonable certainty.

Risk Characterization

Risk characterization is the description of the nature and the magnitude of risk to humans (including attendant uncertainty) that could result from the use of a product in water treatment. In this process, health effects associated with the use of the product are predicted on the basis of both exposure and dose-response data.

Uncertainties in the Risk Assessment Process

Much effort has been devoted to formulating guidelines for carcinogenic risk assessment. Nonetheless, much controversy still surrounds the process because of the substantial uncertainty surrounding the extrapolation from animal data to humans and from high to low levels of exposure. Guidelines are especially necessary in the face of such uncertainty in order to establish consistency in the interpretation of specific types of data and in the selection of mathematical extrapolation models.

Much of the uncertainty in carcinogenic risk assessment comes from the lack of knowledge about the mechanism underlying carcinogenic processes. The unique aspects of carcinogenesis in contrast to other toxicological end points (which require an estimation of risk even at very low levels of exposure) is the quantal nature of the carcinogenic response and the assumption that the severity of the response (malignancy) is unchanged with diminishing dose. By contrast, for almost all other toxicological end points, both the incidence and the severity of effects diminish with decreasing dose to the extent that the toxic effects become trivial at low dosage. Hence, there is much more confidence in the use of safety factors with non-carcinogenic toxic response then with carcinogenicity itself. Mutagenicity shares the quantal nature of response with carcinogenicity, and more is known about the mechanism of action

of mutagens than of carcinogens. However, there is a much greater ambiguity about the nature of the deleterious health consequences of mutagens. Nevertheless, for these two end points there has been the most formalized development of risk assessment guidelines.

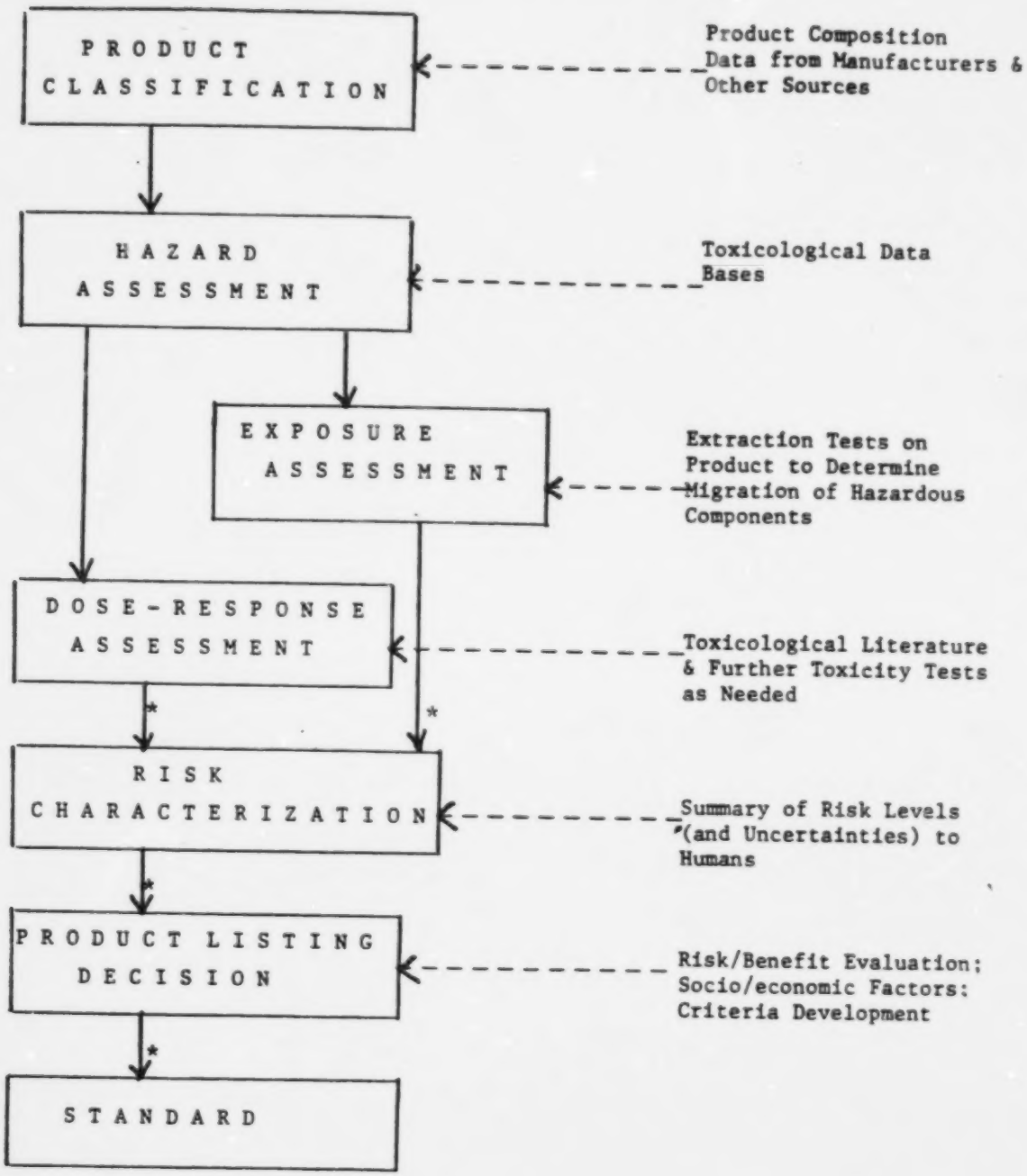
STANDARD-SETTING AND CERTIFICATION

In principle, the certification (or rejection) process involves the evaluation of risk data associated with the proposed use of a particular product. In practice, however, most products submitted for approval will be evaluated according to a set of guidelines or protocols that are unique for each product category. The result of the evaluation will then be compared to those recommended in the standard and decisions can be made in a more or less routine fashion. Except in unusual cases, the process and the final decision can be the responsibility of people who are technically competent but who are not necessarily the most knowledgeable experts in the field. However, all standards, protocols, and guidelines developed must be codified by such experts. Thus, the certification program consists of two essential activities: the development and codification of guidelines and protocols (standard-setting) and the comparison of products to these standards in decision-making (certification).

Standard-Setting

The first task in the establishment of the certification program for water additives will involve the development of a procedure to evaluate a given type of product and a set of criteria to use in decision-making (Figure 4-2). Initially, water treatment products will probably be classified according to type of product (pipe, paint, gasket or other connecting materials, polymeric coagulants, etc.) and further classified by specific type (e.g., polyvinyl chloride (PVC) plastic, asbestos-lined concrete pipe, or polyacrylamide coagulant). For each category, a procedure will be developed to identify the likely components in the product from the information supplied by manufacturers and other sources. If possible, risk will be characterized by following the procedure described in the previous portion of this chapter. Following completion of the risk assessment, a decision must be made whether or not to accept the products in this category for use in water treatment, and, if so, what criteria should be met for acceptance. For acceptable product categories, the result will be the development of a standard, similar to Standard 14 of the National Sanitation Foundation for evaluation of plastic pipe (appendix B).

There are three essential components of each standard: a summary of the review procedure; laboratory procedures or references to procedures for evaluation of products in this category, including extraction, analysis, and bioassay; and, action levels, i.e., maximum impurity levels, for acceptance or rejection of a product based on test results.



*Critical Decision point by EPA or Certification Board.

FIGURE 4-2

Standard-Setting Procedure for Water Treatment Additives

Ranking of Products for Standard Setting. The EPA has indicated that a backlog of 2,300 products exists for which approval is required, and that new products will be forthcoming. To address this backlog, the third party must develop a ranking system using, among others, the following criteria:

- extent of use of the product type; and,
- toxicity of known constituents in the product type.

Toxicities may be estimated for direct additives such as polymeric coagulants from maximum expected dose levels, and available toxicological data. It may be possible to use quantitative structure-activity relationships (SARs) such as those described by NRC, 1984. For indirect additives, in the absence of any extraction data, estimates of exposures can be made from SAR models to supplement toxicological data.

Public Participation in Standard-Setting. The committee discussed several means for public participation in the standard-setting process. This would appear to be a necessity if the EPA continues to be active in the process, as the committee prefers. Even if the EPA does not participate in a formal decision-making process, the committee recommends that the agency should be represented on the certification board and that it publish in the Federal Register each standard before formal adoption. If publication in the Federal Register is not possible, the certification board should take the responsibility to publish each standard before adoption in the appropriate public media. In certain cases, it may also be desirable to convene public meetings. In addition, the third party should periodically publish its lists of standards in trade journals such as the Journal of the American Water Works Association.

Public participation may also be enhanced by representation on the certification board from public interest groups (see page 16). Care should be taken to assure participants have appropriate backgrounds so they can contribute to the process.

Certification Decision-Making

Once a standard has been developed for a given product category, individual products in that category may be evaluated for certification. It is expected that the third party will be responsible for this duty, utilizing procedures developed during the standard-setting phase, and enumerated in the standard for that product type. By and large, it is expected that this is a process that the third party can execute without approval of the EPA.

Figure 4-3 is a flow diagram which illustrates the process by which a product is certified or rejected within the third party Options B and C. The process begins with the decision of a manufacturer to submit a product for certification. The dossier required by the third party for each product

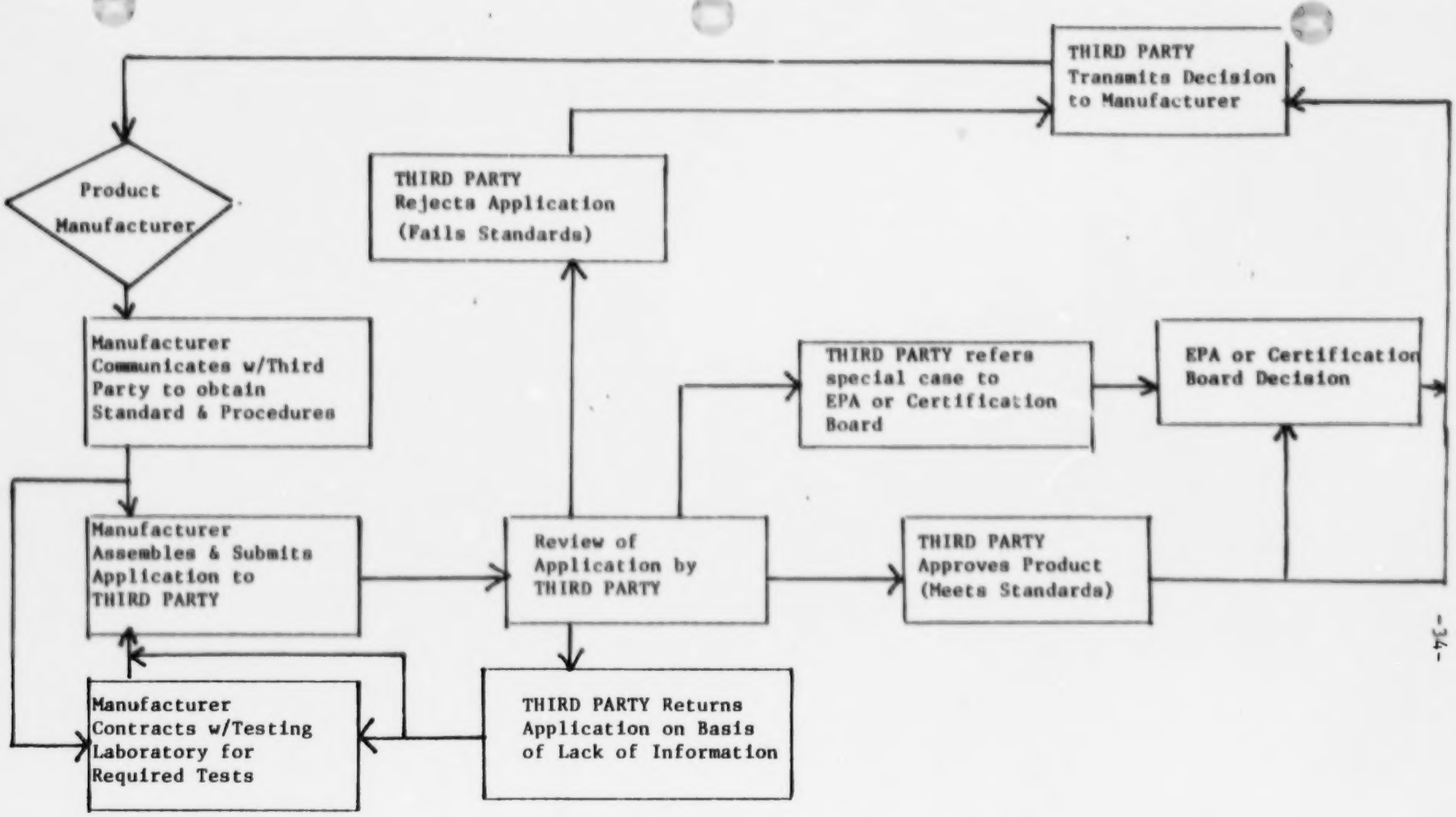


FIGURE 4-3
Flow Diagram for Product Certification Within Options B and C.

will then be supplied by the manufacturer. The dossier should contain:

- Description of the product and intended-uses;

- Manufacturing process used, raw materials, including ranges of amounts used; likely contaminants and by-products;

- Each contaminant, raw material, or by-product identified must have the proper chemical name and CAS Registry number (if available), level present or expected in product, and summary of available toxicity data;

- History of product use in the water industry including whether it is a new product, or the evaluation of product currently in use. If it is a currently used product, the dossier should include the history of use, data used for original approval, products currently used for similar technical effect;

- Summary list of compounds of potential concern (from 3 above);

- Product test data includes results of extraction/analysis tests for specific compounds listed above, the description of extraction tests and analysis procedures used, name of laboratory conducting tests, results of tests including replicate data and other quality assurance procedures followed, and conclusions derived from analysis of the test data;

- Other product test data (including nonspecific tests and bioassays) and other information from manufacturer or testing laboratory.

In most cases, the review will be a routine matter. Exceptional cases are referred to the EPA (Option C) or the certification board (Option B), who can then reject or approve the product, or defer decision. The basis of a deferral may be that more information is needed on the particular product components that may require further toxicity tests, or that further information has been revealed which suggests that a standard needs to be revised or developed. Illustrations of routine and non-routine cases are as follows:

- Product X is categorized as a polymeric additive primarily consisting of polyacrylamide with no impurities except acrylamide monomer. The product is tested according to the protocols for the standard for this type of product and the test shows a level of residual monomer below the maximum allowable limit (the action level). The third party notifies the manufacturer that the product is approved to be used in water treatment below a specified maximum dose level. This notification would not be subject to review by the EPA or the certification board;

- Product Y is categorized as an epoxy-based paint with inorganic pigments. The paint is applied to test coupons and exposed to water for a specified period of time according to the protocols for the standard for this type of product. Analysis of the test extracts reveals levels of the contaminants of concern which are lower than the action levels specified in the standard. However, GC traces reveal another major component of the extracts which is subsequently identified by GC/MS as a compound not included in the standard. Preliminary assessment by the third party indicates that the compound may be toxic at the exposures predicted from the tests. The manufacturer is notified that the case has been referred to the EPA (or the certification board) for risk characterization and for an approval decision.

ROLES OF PARTIES WITHIN OPTIONS C AND B

The previous section of this chapter describes the procedures of standard setting and certification which would be involved in either Option C or Option B. The roles of the various parties will be different in the two options, and as stated previously, the committee recommends a role for the EPA in Option C. The principal difference between Option C, and Option B, is in the role of the EPA. In Option C, the EPA maintains an active role in standard-setting and oversight of the program, while delegating to a third party substantial operational responsibility. In Option B, the EPA is replaced by an external board of experts (certification board) which has final decision-making authority. In both options, the third party is delegated authority to make routine product approval recommendation decisions, but only within the context of specific standards approved either by the EPA (Option C) or the certification board (Option B).

The roles of the various parties within Options C and B are listed in Table 3-1. For emphasis, these are repeated below.

Role of the Manufacturer

In both Options C and B, the manufacturer submits an application to the third party. The application dossier should include product test data including extraction and bioassay data obtained in strict compliance with procedures specified in the appropriate standard.

Role of the Testing Laboratory

In some cases, the manufacturer may choose to contract with a certified testing laboratory, rather than to obtain certification for its own testing facilities. The testing laboratory will be familiar with the requirements of the appropriate product standard and will supply the test results in a form suitable for the product application dossier. All laboratories selected to supply data must adhere to what are commonly understood to be Good Laboratory Practices (GLP) either as defined by the EPA or the FDA.

Role of the Third Party

The third party has several duties in conjunction with the certification of a product. It receives the application; reviews it for completeness and accuracy; communicates with the manufacturer regarding the status of the application; constructs a dossier on the product application, including all available data on the product, bioassay data on its principal constituents, calculations on risk extrapolations and statistics it feels are justified. It also submits a recommendation regarding approval, rejection, or deferral of decision on the product.

The third party should act in certification decisions only within the context of specific standards approved by the EPA or the certification board, depending upon the option. In cases where the product clearly fails or passes the standard, the third party will communicate the required decision to the manufacturer immediately. In the event that the review indicates unknown or uncertain levels of risk associated with the use of the product, the third party is required to refer the case to the EPA (Option C) or to the certification board (Option B).

The third party should also be responsible for the development of a modern data storage and retrieval system, containing up-to-date information on product types, known or suspected contaminants, and all previous cases handled by the approval process.

In addition, the third party acts as coordinator of standards development. This would entail recommendations to the EPA or the certification board of protocols and procedures to be used in the evaluation of a given type Y product (see page 36), and of action levels to be specified in the standards (e.g., maximum allowed contaminant levels). Procedures and criteria to be used in the selection of certified testing laboratories would also be recommended by the EPA or the certification board for approval.

Role of the EPA or the Certification Board

The EPA or the certification board should be the final authority in the development of standards and in review of the work of the third party. Standards recommended by the third party should be reviewed initially by the EPA or the certification board, and approved or modified as necessary. Also, in the initial standard-setting process, it may be desirable to seek additional expert help in the form of an advisory board.

The EPA or the certification board should request a periodic review of standards, and an annual review of the decisions made by the third party.

Role of Advisory Bodies

It is recommended that in Options B and C, additional expert advice be solicited either by the third party or the EPA (certification board). The advisory board should be made up of experts from the fields of toxicology, biostatistics, risk assessment, water treatment and analytical chemistry, chosen so as to complement the expertise of the other parties. The advisory board should be selected by an organization that is not a party in the process.

The advisory board should work closely with the third party to ensure that the protocols for assessing migratory characteristics, extraction conditions and techniques, analytical methods and tier testing sequence are appropriate to define the standard. This process would be repeated for each new product type.

The advisory board should advise the third party on the preparation of a priority list that the third party will use to select an order of evaluation for chemicals currently in use, and should conduct a periodic review of the third party process, including the standards and protocols being used by the third party.

In addition, the advisory body should conduct an evaluation of the third party process on a periodic basis.

The advisory body referred to in the above should not be confused with the certification board.

OTHER DETAILS OF THE THIRD PARTY PLAN

The following is a series of observations and recommendations regarding the implementation of the third party plan.

- The system of product approvals could be paid for either from user fees or by an assessment to water utilities. The former appears to be more workable and would place the burden of costs on the manufacturers seeking approval of their products. A fee structure should be established which separates the cost of testing from the costs associated with the evaluation of the application. Ideally, testing and approval functions should be entirely separate.

- Manufacturers with appropriate capabilities, and operating within what are generally understood to be Good Laboratory Practices (GLP) should be allowed to submit their own product test data, provided that documentation is presented to show that standardized protocols have been used. In all cases, however, any laboratory chosen to prepare submission data should meet GLP requirements.

• Testing laboratories should be selected on the basis of the following criteria generally recognized as GLP. Some of the qualifications examined during the selection process include:

- Staff: people performing technical studies and required to make technical judgements on a regular basis comprise what percentage of the total professional staff? What percentage of the technical staff regularly perform work in analytical chemistry or toxicology, and of these, how many have degrees and training and are professionally certified in toxicology, analytical chemistry or a related discipline?

- Experience: How many toxicologic and extraction studies have been carried out? Number of projects the facility has originated, won competitively as principal investigator, or as subcontractor. For each of these categories, for whom has the work been done? For each category, what is the value of the work in percentage of total dollars of income of the establishment?

- Reports and Publications: Number of reports involving toxicology and extraction tests written. Number published, and peer-reviewed. Number of critical reviews written. Peer-reviewed publication histories of the technical staff.

- Laboratory: Need to subcontract testing. Criteria used in the selection of subcontractors. Organization performs its own laboratory work, all or in part. State or federal certification and quality assurance programs.

- Regulatory Involvement: History of regulatory agency interaction. Experience in federal and state regulation and compliance procedures.

- Expedition: Ability to deliver test data in a specified period of time.

• Meetings of the EPA or the certification board to review third party decisions and to take up special cases should be held on a bimonthly basis.

• Reevaluation of individual products should be carried out on a regular basis and standards should be reevaluated every five years, or when new information becomes available in either case.

• The EPA or the certification board should act as a board of appeals in cases of disagreement with a third party decision. Appeals to the EPA or the certification board should contain documentation that there are data the third party did not evaluate or that the interpretation of the data submitted is incorrect. In addition, all appeals must begin with a request for reevaluation of the product by the third party.

- Reevaluation of standards is more efficient with the use of a modern automated data storage and retrieval system. It is recommended the third party have the capability of such storage and retrieval and that this system contain files on each product and each component previously considered by the third party, and should be updated constantly with new information from all credible sources.

- Information exchange with federal agencies and other parties involved in biotesting of compounds and risk assessment is important, therefore, participation of representatives from the EPA or NIH on the certification board or on the advisory boards of the third party is strongly recommended. This will ensure that the third party is aware of and able to adopt standardized procedures should they be developed within government agencies.

CHAPTER 5

ANALYTICAL PROCEDURES EVALUATING DRINKING WATER TREATMENT ADDITIVES

The evaluation of drinking water treatment additives as possible sources of potable water contamination has been the subject of numerous investigations. Sun et al. (1982) proposed a testing protocol to evaluate levels of chemical contamination, including metals, specific organic compounds, and asbestos fibers. As stated in Chapter 2, the National Sanitation Foundation has developed protocols for this purpose, especially for leachates from metal and plastic pipes. In the Netherlands, the testing of water treatment chemicals is carried out by KIWA (The Netherlands Waterworks Testing and Research Institute) in conjunction with the Commission on Health Aspects of Chemicals and Materials in Drinking Water supply. Similar testing facilities exist in other western European countries including West Germany, France, and Belgium. Protocols developed by these organizations bear many similarities.

The principal objectives of such tests are to determine what specific contaminants of concern are leached into the water under conditions that simulate actual use conditions; what concentrations of those are present in these leachates; and in the absence of data on specific contaminants, what long- and short-term toxicities of the leachates can be evidenced by various bioassays. Thus three test protocols should be developed to accomplish these three objectives.

The committee has elected to discuss extraction and analysis procedures not in the context of a literature review but, rather, in terms of the basic principles that should be followed to develop and implement the tests.

MATERIALS TO BE TESTED

The term "drinking water additives" refers to all forms of substances that come in contact with water in its collection, treatment, storage, and distribution. These include pipe materials and connecting parts, such as gaskets, solders, or joints, and any liners in the pipes; certain parts of valves and pumps, such as internal parts and lubricants; reservoirs and basins, including any parts therein, such as sludge scrapers, weirs, and liners; contact treatment chemicals, such as resins, granular activated carbon, and other filter media; and direct chemical additives such as alum, lime, synthetic polymers, and others (Note 1).

STANDARDIZED PROTOCOLS

A water treatment additive must pass a series of extraction tests conducted according to standardized protocols before it can be approved. Each protocol must be specific for a given type of water treatment additive and must clearly describe the conditions under which the test is to be carried out, directions for interpretating of the experimental data obtained in the test, and a specified maximum contaminant level allowed for an additive to pass the test.

Appendix B is a typical protocol taken from National Sanitation Foundation Standard 14 for plastic pipe. This protocol prescribes the measurement of certain metals, tastes, and odors as well as trihalomethanes, phenols, total dissolved solids, and residual vinyl chloride monomer, which migrate from the pipe during specific tests (Note 2).

TEST CONDITIONS

Two types of tests are used, static and dynamic. In both types, the water treatment additive is placed in direct contact with water. The difference is that the static test is carried out in a closed system with a specific volume of nonflowing water, whereas the dynamic test involves water flowing at a specified rate over the additive. Since water use is usually in a dynamic (flowing) condition, dynamic tests are more representative of use conditions. However, since dynamic tests require more elaborate equipment and are generally more complicated, static tests are favored, provided appropriate correlation factors can be established to relate the results of the tests to use. In exceptional cases, static tests are more representative than dynamic tests, e.g., when water is allowed to sit in pipes with no flow for several hours or perhaps days. This situation occurs daily in normal use of drinking water, where the last water drawn into the pipes in the evening stands until the following morning when the tap is first opened. The choice of a static or dynamic test protocol is dictated by considerations of both actual use conditions and factors related to the conduct of the test itself, such as ease, convenience, cost of equipment, and time.

Other important test conditions may be divided into three categories:

- those related to the quality of water to be used in the test, such as pH, alkalinity, or hardness;

- those related to the physical or mechanical factors associated with the test, such as temperature, duration, or rate of flow or stirring; and,

- those related to the analytical methods used to determine the nature and levels of contaminants leached into the water during the test.

Test Conditions Related to Water Quality

Water quality affects leaching. For example, in tests involving asbestos-cement pipe, corrosive water will dissolve the cement binder and release asbestos fibers into the water. Also, different heavy metals will be leached at various rates from metal pipes under different conditions of pH, hardness, and other water quality factors. Generally speaking, the use of highly purified (laboratory grade) water is not considered to be appropriate except when background levels of impurities might obscure test results, as in the measurement of trihalomethanes. It is not necessary, of course, to use a natural water; laboratory grade water may be supplemented with chemicals to create a composition with specific hardness, pH, or other characteristics.

Sun et al. (1982) and Packman (1971) have described some types of water, buffers, and pH's used in extractions. Of particular interest are the specifications given by Packman et al. (1971) in which three pH buffers are required. NSF Standard 14 specifies four "standard" extract waters with different pH, hardness, and chlorine content. KIWA specifies only a single extraction water: distilled water containing 150 mg of carbon dioxide at pH 4.6. A more recent procedure proposed for adoption in Belgium specifies two test waters. One containing 420 mg sodium bicarbonate and 1 mg/l of active chlorine per liter; and one the same as the KIWA specification.

More recently, the EPA has focused attention on the use of water chosen to maximize leach rates, so-called "aggressive" water. It has also discussed the effect of carbonate and pH on the solubility of lead and cadmium in water and has identified regions where leach rates should be highest. In studies of this type, it may be possible to select water quality specifications for leach tests that have a better scientific basis than those used in the past.

Test Conditions Related to Physical Factors

An important physical property associated with migration of substances from drinking water additives is temperature. Tests should be conducted at a temperature representative of general use conditions (e.g., 20°C to 35°C) and at a higher temperature such as that in a hot water heater (80°C to 90°C) if the product is to be used in the home.

Another factor of importance in extraction tests is the ratio of additive to water volume. For direct additives such as polymeric coagulants, this corresponds to the amount of the additive. The conservative approach is to use in the tests a level representing the maximum amount of the additive likely to be used in drinking water treatment. For contact materials, such as pipes, and liners, the ratio of surface area of the material to volume to water used is important.

Other physical factors of importance in migration tests include those associated with the physical apparatus itself, e.g., the geometry of the test vessel, rate of stirring (if any), presence of headspace in the vessel, and prerinsing cycle. In dynamic tests, the flow rate of the water is an important factor. Preparation of the material to be tested is also important, especially for contact materials.

Correlation of Test Conditions with Actual Use Conditions

Test conditions covering the preparation of the sample and exposure conditions must be specified in great detail. In the development of protocols for this purpose, the principal criterion should be to use conditions most closely simulating actual use conditions. However, in order to minimize costs and time associated with the testing of the product, it is desirable to use a minimum number of test protocols. Ideally, a single protocol could be used for a variety of different types of materials, e.g., pipes, coatings, and gaskets. One approach is to interpret these tests by applying a correlation factor (or correction factor to use the KIWA terminology). Such factors can be applied to test results to make them more consistent with actual exposure conditions. In addition, correlation factors are necessary because one

must use surface to volume ratios for tests that are much larger than those experienced in actual use conditions in order to analyze trace contaminants in the products.

ANALYSIS OF TEST EXTRACTS

Once a water treatment additive has been exposed to a test water, there remains the task of determining whether contaminants have been transferred from the additive to the water and their possible health implications. The approaches that have been used for this purpose may be classified into three categories:

- non-specific tests
- specific tests
- bioassays or toxicological tests

Non-Specific Tests

This low technology approach to extract analysis is preferred for its economy rather than for its scientific basis. Nonspecific determinations include chemical oxygen demand (COD), total organic carbon (TOC), or total residue. Other nonspecific determinations are taste and odor thresholds (determined by panels) and certain spectroscopic properties such as fluorescence emission and ultraviolet absorbence. Nonspecific analytical determinations are of minimal value in assessing toxicological risks associated with the use of the water treatment additive. In general, correlations have not been established between levels of the nonspecific determinations and toxic effects. Moreover, nonspecific determinations do not necessarily act as surrogate parameters for specific toxicants. This is due in part to the fact that nonspecific determinations often have rather high limits of detection and also because they are subject to interferences by nontoxic substances in the sample. For example, TOC has detection limits of approximately of 100 ug/liter and TOC so measured may include matrix components that are nontoxic.

The use of nonspecific determinations for monitoring various types of environmental samples is a goal shared by several agencies and is therefore not unique to the testing of water treatment chemicals. At the present time, however, the use of nonspecific determinations is not a promising approach for correlating toxicological properties of concern, and they should be used only in conjunction with specific tests and bioassays.

Specific Tests

In this report, the term specific tests refers to the determination of the levels of specific chemical substances in test extracts. By and large, these may be divided into tests for inorganic and organic substances. The selection of tests to be used is based on the information available to the testing laboratory (or governing agency) concerning the contaminants to be found in the product of interest. This information may be common knowledge, or it may be supplied by the manufacturer with its application for product approval.

Inorganics. Standard methods for inorganic elements, such as heavy metals, and for radicals, such as nitrate, and fluoride, are well known (APHA,

1981). In general, these methods have micrograms per liter and lower detection limits and are well suited for the analysis of test extracts.

Organics. Standard methods for certain classes of organic compounds are also well known. Mostly these refer to organic compounds that are amenable to analysis by gas chromatography (GC). The EPA has developed a series of methods referred to as the 600 Series, some of which are based on GC with conventional detectors (flame ionization or electron capture). However, the most advanced and preferred methods use GC in combination with mass spectroscopy (GC/MS) for confirming the identity of the test substance. Series 600 methods are most efficient for very volatile organics, which can be separated from the water matrix by some type of purging procedure, and are less successful for less volatile materials, which require another preseparation step such as solvent extraction or resin accumulation. Nonetheless, if the compound to be analyzed is known, a sufficiently accurate and precise separation/analysis procedure can usually be developed. Detection limits for GC/MS-based schemes usually are in the low microgram per liter range.

For compounds not amenable to GC or GC/MS, because of difficulties in either the GC or the MS component of the scheme, alternative methods may sometimes be used, depending on the test substance. High performance liquid chromatography (HPLC) is capable of higher resolution and promises to provide separation capabilities for most nonvolatile organics and many inorganics. The primary deficiency of HPLC for trace analysis is the lack of proven interfaces to mass spectrometers and other spectroscopic aids to confirm structure. Recent developments in thermospray interfaces for HPLC/MS systems show promise of alleviating this deficiency, at least for many types of organic substances. Also, relatively new applications in MS, such as chemical ionization, atmospheric pressure ionization, fast atom bombardment, and high resolution techniques, may aid in the identification and analysis of HPLC fractions.

High molecular weight organics represent a class of substances that are difficult to separate with high resolution and also to identify. Fortunately, there is little evidence to suggest that high molecular weight organics are of toxicological significance. Until that evidence is available, it is unlikely that these substances will be of much concern as drinking water impurities. High molecular weight humic substances, which are ubiquitous in drinking water sources, are known to form complexes with hydrophobic organic compounds. However, this bears little relevance to the impurity of drinking water additives except as noted in the section entitled Test Conditions Related to Water Quality.

Bioassays or Toxicity Tests

A substantial number of toxicity tests are used to predict human response, including: acute toxicity (oral, dermal, parenteral, inhalation, and eye); subchronic oral toxicity (14 day, 28 day, 90 day, 6 month, and 12 month); skin sensitization; subchronic dermal toxicity (21 day, 90 day); subchronic inhalation (90 day); subchronic neurotoxicity (90 day); delayed neurotoxicity; teratology; multigenerational reproduction; toxicokinetics; chronic oral toxicity; carcinogenicity; genetic toxicity. Protocols for carrying out these tests and interpretations of their strengths and weaknesses have been

published by the NRC (1984); the FDA (1982); and the organization for Economic Cooperation and Development, (OECD, 1981). A variety of automated data bases can also provide information on chemicals (NRC, 1984). These include Chemline, Chemical Abstracts, Toxline, Cancerline, Medline, Biosis, and Agricola.

Two approaches to tier testing can serve as models for use in the toxicological evaluation of water treatment chemicals. One was developed by the Food Safety Council (1978) and the other as a proposal for internal use by the FDA. Both call for testing for acute toxicity and genetic toxicity (as a predictor of carcinogenicity) as a minimum. The Food Safety Council tree found in Figure 5-1 contains the elements of exposure and shows the progression from acute to chronic toxicity testing with ultimate decisions (starred end points) based, in part, on nontoxicological considerations.

The FDA approach is more specific in terms of levels of concern about exposure concentrations, chemical structure, and specifications of appropriate tests for given levels of concern (FDA, 1982). The exposure category, and the estimated toxicity (derived from molecular structure categories A, B, and C), together determine three distinct Levels of Concern.

Following are descriptions of the structure categories:

- Category A. Molecular structures of low toxicity, for example, simple aliphatic, noncyclic hydrocarbons, fats and fatty acids, sugars, polysaccharides, and normal human biochemical constituents.

- Category B. Molecular structures of some toxicity, including, for example, nonconjugated olefins, polypeptides, formates, and quaternary amines.

- Category C. Molecular structures with substantial toxicity, such as epoxides, unsaturated lactones, nitroso groups, and carbamates.

The concern levels are defined as follows:

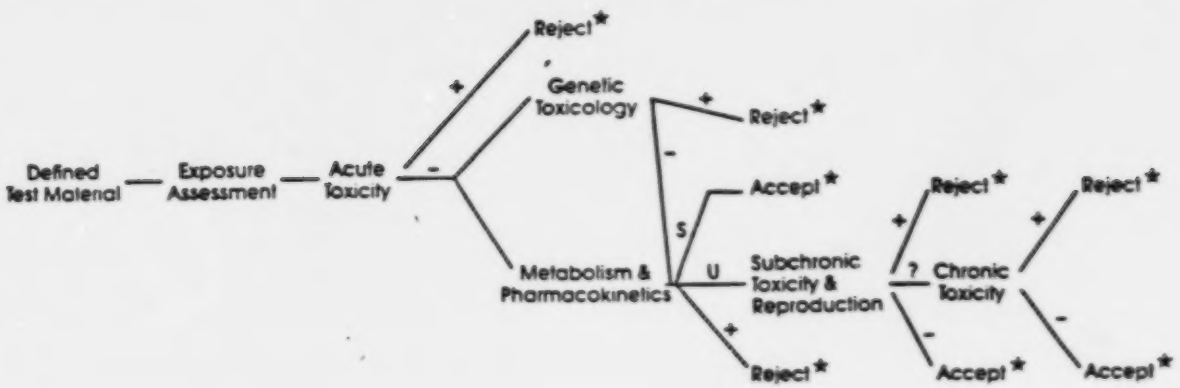
- Level I: Least Concern. Suggested minimum testing includes a short-term feeding study (28 days in duration) and short-term tests for carcinogenic potential.

- Level II: Intermediate. Suggested minimum tests include subchronic feeding studies (90 days in both a rodent and a nonrodent species), a multigeneration reproduction study (minimum of two generations) with a teratology phase in a rodent species, and short-term tests for carcinogenic potential.

- Level III: Great Concern. Suggested tests include carcinogenicity and chronic toxicity studies in two rodent species, a long-term (1 year) feeding study in a nonrodent species, a multigeneration reproduction study (as in Level II), and genotoxicity studies.

The interrelation of structure exposure and level of concern is presented in Table 5-1. Structure activity relationships (SARs) may be used to evaluate molecular structure and to place structures into specific categories. An excellent review of SAR techniques can be found in the report of a recent study on toxicity testing by the National Research Council, (1984).

SAFETY DECISION TREE



+ = presents socially unacceptable risk
- = does not present a socially unacceptable risk
S = metabolites known and safe
U = metabolites unknown or of doubtful safety
? = decision requires more evidence

FIGURE 5-1

TABLE 5-1

	Structure Category		
Level of Concern	A	B	C
I	<0.0012	<0.00063	<0.00031
II	0.0012-0.025	0.00063-0.0125	0.00031-0.0063
III	>0.025	>0.0125	>0.0063

The exposure categories (mg/kg/day) are given in the body of the table in relation to the Structure Category and Level of Concern.

As pointed out in this chapter, the exact conditions and extent of analytical testing and evaluation will depend upon the nature of the additives. However, the priority setting mechanism and test protocols should not place an excessive burden on the evaluation process.

NOTES

Note 1

Direct additives are the subject of a previous study, which resulted in the publication of the first edition of the Water Treatment Chemicals Codex (NRC, 1983). Nevertheless, since the fate of the EPA additives program is not yet clear, it is possible that direct and indirect (contact) additives may eventually be considered for approval by the same process.

The principles discussed in this section apply equally well to direct and indirect additives. Indeed, the first Codex contained procedures for evaluating several direct additives through the use of extraction procedures, which in many cases closely resemble those used for so-called indirect additives. In one such procedure, for example, activated carbon (AC) is extracted with water of specified quality, e.g., pH, for the determination of metals likely to migrate into the water during actual use.

Note 2

In Standard 14, residual vinyl chloride monomer is measured by extraction with an organic solvent N,N-dimethylacetamide, rather than by extraction with water. It is therefore not necessarily a measure of monomer that is likely to migrate from the pipe during use. The measurement of total impurity levels of this type is an alternative to extraction tests using water, but it is not generally preferred. Total impurity levels are generally felt to be irrelevant unless it is shown what amount of the impurity is actually likely to enter the water under conditions close to actual use.

REFERENCES

Albert, R. E., R. E. Train, and E. Anderson. 1977. Rationale developed by the Environmental Protection Agency for the assessment of carcinogenic risks, J. Natl. Cancer Inst. 58(5):1537-1541.

(APHA) American Public Health Association. 1981. Standard Methods for the Examination of Water and Wastewater. 15th ed. American Public Health Association, Washington, D.C.

(ASTM) American Society for Testing and Materials. 1975. The Voluntary Standards System of the United States of America. An appraisal by ASTM, Philadelphia.

(AWWA) American Water Works Association. 1970. Standard for Aluminum Sulfate. Pub. No. B403-70. American Water Works Association, Denver.

Baram, M., D. Sandberg, L. Dufault, K. McAllister. 1981. Managing risks to health, safety and environment by the use of alternatives to regulation. N. Engl. Law Rev., 16(4):657-687.

EPA (U.S. Environmental Protection Agency). Environmental Criteria and Assessment Office. 1984a. Approaches to risk assessment for multiple chemical exposures. Pub. No. 600/9-84-008. EPA, Washington, D.C.

EPA (U.S. Environmental Protection Agency). 1984b. Drinking water technical assistance; disposition of the federal drinking water additives advisory program; development of a private sector organization. Fed. Regist. 49(97):21004.

EPA (U.S. Environmental Protection Agency). 1980. Toxic Substances Control Act Chemical Substances Inventory. EPA, Washington, D.C.

EPA (U.S. Environmental Protection Agency). 1976. Interim procedures and guidelines for health risk and economic impact assessments of suspected carcinogens. Fed. Regist. 41:21404.

(FDA) Food and Drug Administration. 1982. Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food. Food and Drug Administration, Washington, D.C.

Food Safety Council, Scientific Committee. 1978. Proposed system for food safety assessment. Food and Cosmetics Toxicology, Vol. 16, Supplement 2, Washington, D.C.

Hamilton, R. 1978. The role of nongovernmental standards in the development of mandatory federal standards relating to safety and health. Report prepared for the Committee on Licenses and Authorization, Administrative Conference of the United States, Washington, D.C.

Hanson, H. F., A. M. Perler, J. Saxena. 1983. The regulatory framework for the control and use of organic polyelectrolytes in drinking water. Unpublished. Paper presented at the 1983 Annual Meeting of the American Water Works Association, Las Vegas.

Interagency Regulatory Liaison Group, Work Group on Risk Assessment. 1979. Scientific bases for identification of potential carcinogens and estimation of risks. J. Natl. Cancer Inst. 63: 241-268.

Miyares, R. J. 1983. Controlling health hazards without Uncle Sam. Technol. Rev. 86 (5):14.

NRC (National Research Council). 1982. Identifying and Estimating the Genetic Impact of Chemical Mutagens. National Academy Press, Washington, D.C.

NRC (National Research Council). 1983. Risk Assessment in the Federal Government. National Academy Press, Washington, D.C.

NRC (National Research Council). 1984. Toxicity Testing, Strategies to Determine Needs and Priorities. National Academy Press, Washington, D.C.

NRC (National Research Council). 1983. Water Treatment Chemicals Codex. National Academy Press, Washington, D.C.

OECD (Organization for Economic Cooperation and Development). 1981. Guidelines for Testing of Chemicals. OECD, Washington, D.C.

Office of Science and Technology. 1984. Chemical carcinogens; review of science and its associated principles. Fed. Regist. 49(100):21595.

Packman, R. 1971. Extraction and testing procedures. J. Water Treat. and Exam. 20:108.

Sun, C., C. Chen, F. Zefran, and J. Price. 1982. Study and evaluation of chemical leaching tests. Report to the U.S. Environmental Protection Agency, Washington, D.C.

Travaglini, V. 1980. Reference to standards in the United States. ANSI Reporter.

U.S. Office of Management and Budget. 1982. Issuance of circular No. A-119, Federal participation in the development and use of voluntary standards. Fed. Regist. 47(211):49496.

federal register

Thursday
May 17, 1984

Part IV

Environmental Protection Agency

Drinking Water Technical Assistance; Disposition of the Federal Drinking Water Additives Advisory Program; Development of a Private-Sector Voluntary Standard Organization; Notice

ENVIRONMENTAL PROTECTION AGENCY

[OW-FRL 2589-4]

Drinking Water Technical Assistance; Disposition of the Federal Drinking Water Additives Advisory Program; Development of a Private-Sector Voluntary Standard Organization

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Office of Water (ODW) has operated an advisory program designed to give technical assistance to concerned parties on the use of drinking water additives. EPA now proposes to terminate major elements of this program and to establish a private-sector program which will offer assistance in evaluating drinking water additives. EPA Solicits proposals from qualified nongovernmental, nonprofit organizations for assistance under a cooperative agreement designed to foster the inception of a credible and efficient program in the private sector. This notice explains the requirements and deadlines for submitting statements of qualifications and proposals for that assistance. EPA will decide whether one of the proposals is likely to result in a successful program; and if so, EPA may award the cooperative agreement and initiate the process for the development of such a program.

DATE: May 17, 1984. Please submit written comments to the address below by July 2, 1984. A Preproposal conference for potential applicants is scheduled on July 23, 1984, at EPA in Room 3906, 401 M Street, SW., Washington, D.C. Full proposals are due by September 4, 1984.

ADDRESSES: Submit Comments to comment Clerk, Criteria and Standards Division, Office of Drinking Water (WH-550), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. A copy of all comments will be available for review during normal business hours at the EPA, Criteria and Standards Division, Room 1109ET, 401 M Street, SW., Washington, D.C.

Submit applications and proposals to: Comment Clerk, Criteria and Standards Division, Office of Drinking Water (WH-550), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Arthur H. Perler, Science, and Technology Branch, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. Or call, (202) 382-3040.

I. Introduction

The Safe Drinking Water Act (SDWA) of 1974 (42 U.S.C. 300f *et seq.*) provides for enhancement of the safety of public drinking water supplies through the establishment and enforcement of national drinking water regulations. The Environmental Protection Agency (EPA) has the primary responsibility for establishing the regulations and the States have the primary responsibility for enforcing such regulations. If a State fails to assure enforcement of drinking water regulations, EPA may move to enforce the regulations by taking certain actions against the State or the public water system owner or operator. The regulations control contaminants in drinking water which may have any adverse effect on public health. (Section 1412, 42 U.S.C. 300g-1). The regulations may include maximum contaminant levels (MCLs) for specific contaminants, treatment techniques where no MCL can feasibly be ascertained, and monitoring requirements for regulated and unregulated contaminants. (Sections 1401, 1412, 1445, 42 U.S.C. 300f, 300g-1, 300i-4). In addition, EPA has broad authorities to provide technical assistance and financial assistance (grants/cooperative agreements) to States and to conduct research. (Sections 1442, 1443, 1444, 42 U.S.C. 300j-1, 300j-2, 300j-3).

The Agency has established MCLs for a number of harmful contaminants that occur naturally or pollute public drinking water supplies. In addition to such contaminants, there is a possibility that drinking water supplies may be contaminated by compounds "added to" drinking water, either directly or indirectly, in the course of treatment and transport of drinking water. Public water systems use a broad range of chemical products to treat water supplies and in maintaining storage and distribution systems. Systems may directly add chemicals such as chlorine, alum, lime and coagulant aids in the process of treating water to make it suitable for public consumption. These are known as "direct additives." As a necessary function of maintaining a public water system, storage and distribution systems (including pipes, tanks and other equipment) may be painted, coated or treated with chemical products which may leach into or otherwise enter the water. These products are known as "indirect additives." Unless direct or indirect additives consist of ingredients or contain contaminants for which EPA has promulgated MCLs, the levels of additives in drinking water currently are not regulated by EPA.

While the SDWA does not require EPA to control the use of specific additives to drinking water, EPA has provided technical assistance to States and public water systems on the use of additives through the issuance of advisory opinions on the acceptability of many additive products. EPA has provided this technical assistance pursuant to its discretionary authority in Section 1442(b)(1) to "collect and make available information pertaining to research, investigations and demonstrations with respect to providing a dependable safe supply of drinking water together with appropriate recommendations in connection therewith." Prior to the enactment of the SDWA and creation of EPA, the U.S. Public Health Service (within the Department of Health, Education, and Welfare (HEW)) has provided advisory opinions on use of additives. The authorities of the Secretary of HEW to establish drinking water regulations pursuant to the Public Health Service Act were transferred to the Administrator of EPA under Reorganization Plan No. 3 of 1970. These authorities in the Public Health Service Act subsequently were superseded by the SDWA. Therefore, the Federal Government has for many years provided technical assistance by issuing advisory opinions on the use of drinking water additives.

In 1979, EPA executed a Memorandum of Understanding (MOU) with the Food and Drug Administration (FDA) to establish areas of authorities with respect to control of additives in drinking water. (44 FR 42775, July 20, 1979). FDA is authorized to regulate "food additives" pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA). (21 U.S.C. 301 *et seq.*). Prior to the enactment of the SDWA, the FDA has interpreted the FFDCA's definition of "food" to include drinking water. Both agencies recognized in the MOU that the "passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes." (44 FR 42775). The MOU states that FDA would continue to have authority for taking regulatory action under the FFDCA to control additives in bottled drinking water and in water used in food and for food processing. (44 FR 42776). The MOU agreed that EPA could establish appropriate regulations under the SDWA to control additives in drinking water. The MOU also discussed

Reproduced from best available copy.

A-1

organizations for receipt of financial assistance under a cooperative agreement, designed to assist in the establishment of a private-sector, third-party drinking water additives evaluation program. If EPA determines that one of the proposals received pursuant to this notice is highly likely to result in a successful private-sector program, EPA may award the cooperative agreement and the selected organization will initiate the process for the constitution of such a program. The financial assistance will be offered pursuant to the SDWA Section 1442(b)(3)(C), which requires that grantees be nonprofit organizations, and subject to the provisions of 40 CFR Part 30. The third-party will provide substantial funding of its own during the term of the agreement and will be self-sustaining thereafter. Competition is expected to stimulate innovative program designs and mechanisms for handling additives within the broad framework that is described in this notice. Proposals are expected from organizations or consortia of organizations with broad experience in standard setting, drinking water technology, toxicology and public health matters.

The project period shall be 36 months, and the initial budget period shall be 12 months. The second and third budget periods shall be 12 months each. The successful applicant will receive financial assistance from EPA in the amount of $100,000.00 for the initial budget period. If, in the opinion of EPA, the program appears likely to achieve long-term success, and at the option of EPA, budget periods 2 and/or 3 may be funded by EPA with the assistance in year two not to exceed $50,000.00 and the assistance in year three not to exceed $35,000.00. Applicants shall provide for a minimum of 5% non-Federal funds cost sharing in each budget period.

V. Procedure for Submission, Evaluation and Award of This Cooperative Agreement

1. On July 23, 1984, EPA will hold a pre-proposal conference for potential applicants. At that time, EPA will make a general statement to interested parties about this proposed program, and EPA staff will answer questions concerning the process. The application package will be mailed on July 30, 1984 to each person requesting one. Requests may be made at the pre-proposal conference, or by mail to the Comment Clerk in the Criteria and Standards Division, ODW (see Addresses Section). A transcription of the EPA statement and of all questions and answers will be sent to each person requesting a proposal application.

2. Applicants should submit the complete application package, consisting of the following documents, to the Comment Clerk designated in the Addresses Section by September 4, 1984.

a. Description of applicant organization and statement of participating organizations;

b. Declaration of "nonprofit" status;

c. EPA Form 5700-12, "Application for Federal Assistance," completed and signed; and

d. Full narrative proposal, based on the minimum qualifications and criteria contained in Section VI, herein. The proposal must specifically address all evaluation criteria described herein. All applicants will be scored and evaluated solely on the basis of their *written* proposals, as measured specifically against the evaluation criteria described herein (the relative importance of each criterion can be ascertained from the weights assigned herein).

3. Upon receipt of the application packages, the Comment Clerk will transmit the proposals of the Technical Evaluation Panel (TEP) Chairman who will initiate the evaluation process. Proposals will be scored according to the criteria and relative weights assigned in Section VI of this Notice. The TEP shall decide which proposal(s) have sufficiently high scores to merit further consideration. Each application which falls within that sufficiently high range will be transmitted to the EPA Grants Administration Division for registration and screening. Once registered and screened, each applicant will be given an opportunity to address deficiencies noted by the TEP. The revised proposals shall be submitted to the Comments Clerk on or before the date specified by the TEP. The TEP shall then score all revised proposals and shall determine which revised proposals fall within an acceptable high range for further consideration. The TEP may request further revisions from high scoring applicants. When the TEP determines that one or more of the proposals:

a. Attains a sufficiently high overall score, and

b. Is not significantly deficient in any evaluation criteria,

then the TEP may recommend, in its report, such proposal(s) to the Source Selection Official (SSO) for selection. If the TEP report recommends more than one proposal for consideration by the SSO, then the report shall contain both a ranking of the proposals according to actual scores and a ranking of the proposals according to the consensus recommendation of the TEP as to the relative overall quality of each proposal. The SSO reserves the right to either make a selection consistent with the recommendations of the TEP, or to determine that none of the proposals are acceptable to EPA. If an award is made, it will be made on or before September 30, 1985.

VI. Evaluation Criteria for the Cooperative Agreement

Applicant organizations or groups must meet and address all of the following criteria and qualifications as a minimum for consideration in the evaluation:

1. (weight = 0; applicants who do not explicitly meet this criterion will be disqualified) Applicant shall be a "nonprofit" organization which is defined as an organization no part of the net earnings of which inure, or may lawfully inure, to the benefit of any private shareholder or individual. For the purposes of this notice, only nonprofit nongovernmental entities will be considered.

2. (weight = 10) Applicant shall demonstrate experience as a voluntary standard body in order to assure that it will offer fair, equitable, and impartial evaluations to the user and supplier industries and to concerned public-sector entities. For the purpose of this notice, a voluntary standard body shall be defined as a private-sector domestic or multinational nonprofit organization, such as industry associations, professional or technical societies, institutes, recognized test laboratories or other groups that plan, develop, establish or coordinate voluntary standards.

3. (weight = 16) Applicant shall demonstrate through clear ties to the water utility industry, manufacturers, States and the scientific community, that it is capable of gaining the confidence of interested governmental authorities, utilities, manufacturers and the public in order that they accept and adopt the third-party's recommendations and standards.

4. (weight = 12) Applicant shall demonstrate that nationally recognized personnel of established expertise in the fields of chemistry, toxicology, engineering, public water supply, regulatory affairs and voluntary standards development are available and committed to work on this project.

5. (weight = 8) Applicant shall demonstrate that it has access to adequate testing facilities and sufficient personnel with appropriate technical expertise to handling the testing. Applicant must have access to EPA

Reproduced from best available copy.

on EPA's computer during the term of the cooperative agreement and be billed for the computer usage. Access of EPA's AIS may also be available after the expiration of the cooperative agreement. It is unlikely that this project alone would justify the cost of a System 2000 license for the third-party. Of course, transfer of EPA's *data*, as distinct from software, raises confidentiality issues and, if proposed, should be addressed in response to item 6, above.

e. (subelement weight = 2) Identification and support of research needs in the additive area. Because ODW sponsors research in closely related areas, this task may be accomplished with the ongoing participation of the Agency.

8. (weight = 10) Adoption of a budget and fee structure for the program which indicates that this program will have permanent financial viability. The applicant shall demonstrate a sufficient understanding of the market for drinking water additives to indicate that the proposed fee structure is reasonable. The financial plan for the program, incorporating the Agency assistance for the first year and the potential reduced assistance in the second and third years, must indicate that the third-party will be self-supporting by the fourth year. This may mean the expenditure of substantial private-sector resources in the start-up phases of the program. Provision of this additional funding during the start-up period will be the responsibility of the third-party. The Agency requires a budget for the fourth year (non-Federal participation) with the application package. The applicant shall provide a complete description of the proposed expenditure of the Federal funds. Sources of additional funds for the start-up phases must be enumerated. The narrative proposal must contain an itemized budget for each budget category in each budget period, and the applicant must complete the sections relating to budget and costs on Form 5700-12.

VII. Request for Comments

EPA requests comments and information on all aspects of the matter of establishing a non-governmental organization of offer technical assistance on the use of additives in drinking water. Specifically, EPA is interested in responses to the following general questions:

1. Will the program proposed in this notice adequately serve the needs of the public, manufacturers, utilities, States and other Federal agencies?

2. Would more formalized regulation and control of additives better protect the public health?

3. Would more formalized regulation and control of additives be more or less attractive, economically, to users and suppliers?

4. Will the proposed program facilitate the introduction of new and improved water treatment techniques?

5. Are the anticipated provisions for confidentiality adequate; will the proposed program require enhanced techniques for handling confidential business information; might the program fail because of the reluctance of maufacturers to reveal trade secrets to private-sector organizations?

6. Should the Agency proceed with this plan to transfer much of the control of drinking water additives to the private-sector, or should the Agency pursue another course of action?

Written comments should be sent to the address indicated in the Addresses Section of this Notice. Comments received on or before the date indicated in this notice will be carefully considered.

Dated: April 27, 1984.

Jack E. Ravan,

Assistant Administrator for Water, Office of Water, Environmental Protection Agency.

[FR Doc. 84-13288 Filed 5-16-84; 8:45 am]

BILLING CODE 6560-50-M

Reproduced from best available copy.

A3

PART 2

LABORATORY PROCEDURES FOR SAMPLE PREPARATION EXTRACTANT WATER EXPOSURE TASTE AND ODOR

SECTION 1. SAMPLES

1.0 REQUIREMENTS: Use a "standard" ratio equivalent to 1 square inch (6.5 cm^2) surface area of plastic sample to 4 ml of extractant water for all exposures.

Table A-II
Standard ratio, sample: extractant water

Plastics Sample Surface Area (Sq. In.)	(cm^2)	Extractant Water Volume (liters)
250	1612.9	1.0
500	3225.8	2.0
1000	6451.6	4.0
100*	645.2	4.0

*nylon only

1.1 PREPARATION: Prepare sample so that entire surface area to be exposed is covered by extractant water. To minimize exposure of cut edges, limit sawing of samples to that which is needed to satisfy this condition. Remove burrs from sawing prior to sample exposure.

Pipes: Cut samples into 5 inch (127.0 mm) sections. If pipe diameter is too large for extraction vessel, split sections lengthwise.

Compounds and Materials: Injection mold, compression mold, or mill and compression mold compounds and materials into flat sheets; cut to provide the required surface area for exposure.

Fittings, Tanks and Special Samples: If size permits, expose samples as received.

Solvent Cements: Spread samples over 10 square inches (64.5 cm^2) of surface on a plastic pipe for at least 72 hours curing time prior to exposure.

1.2 WASHING: Place prepared samples in coated stainless steel baskets for washing. Wash all pipe, plaques and fittings samples in automatic glassware washer using a cold wash cycle. Run washer through cycle with no plastics samples to insure that holding tank contains cold water only. Place baskets with samples in washer, set washer for "detergent wash" and "distilled water final rinse" and run. (EL Detergent 101 and EL Detergent Additive 601 are used for washing; Economics Laboratories, Inc., St. Paul, MN 55102)

1.3 DRYING AND STORAGE: Place baskets with samples in laminar flow hood until they are completely dry.

Remove dried samples from baskets and store in paper bags properly labelled with sample identification number. Fold down tops of bags to prevent dust accumulation.

SECTION 2. EXTRACTANT WATER

2.0 CHEMICAL CHARACTERISTICS: Prepare "standard" extractant water to contain 100 mg/l hardness (as $CaCO_3$) and 0.5 mg/l chlorine in distilled water. Adjust pH to 5.0 ± 0.2 with CO_2.

2.1 REAGENTS: Buffer Stock Solution: Dissolve 3.36 g sodium bicarbonate ($NaHCO_3$) in distilled water. Make up to one liter. Make fresh daily.

Hardness Stock Solution: Dissolve 4.44 g chloride (anhydrous $CaCl_2$) in distilled water. Make up to one liter. Make fresh daily.

Chlorine Stock Solution: Add 7.3 ml sodium hypochlorite (5 percent NaOCl) to 200 ml distilled water. Make fresh weekly. Keep in tightly stoppered bottle. Determine the strength of the chlorine stock solution by diluting 1 ml to 1 liter with standard extractant water, and immediately analyze for total available residual chlorine. Reference this determination as "A." To determine the volume of $C1_2$ stock solution necessary to pipet into the exposure water to achieve a 0.5 mg/l $c1_2$ residual, use the following formula:

$$C1_2 \text{ stock soln. (mls)} = \frac{0.5B}{A}$$

WHERE:

A = Cl_2 equivalent per ml of Cl_2 stock soln.

B = liters of standard extract water.

2.2 WATER: Prepare "standard" extractant water by adding stock reagent solutions to distilled water, as shown in Table A-III.

Table A-III

"Standard" Extractant Water

Distilled Water (liters)	Buffer Stock Solution (ml)	Hardness Stock Solution (ml)	Chlorine Stock Solution (ml)
1	25	25	*
6	150	150	*
12	300	300	*
15	375	375	*

Bubble with CO_2 until pH 5.0 ± 0.2 is attained.
*Note: Reference 2.1 Chlorine Stock Solution.

SECTION 3. EXPOSURE

3.0 VESSELS ONE-LITER EXPOSURES: Use 2-liter beakers to exposure 250 square inches (1612.9 cm^2) of plastics sample in 1 liter of "standard" water. Cover beakers with glass plate or with plastic wrap which has been shown not to contribute detectable levels of parameters measured for conformance with NSF Standard 14, Table I.

EXPOSURES GREATER THAN ONE LITER: Use 9-liter glass stoppered serum bottles for exposure to volumes greater than 1 liter, and battery jars with plate glass covers for samples which are too large to be exposed in 9-liter serum bottles.

3.1 EXPOSURE CONDITIONS: All tests for acceptance, qualification and routine monitoring shall be conducted with the multiple exposure procedure except dip tubes, which shall be tested with single exposure.

Single Exposures: *(Dip Tubes only) Expose for 72*±4 hours at 99±0.5°C.

Multiple Exposures:

Cold Applications Samples:

1. 24±1 hour at 37±0.5°C
2. 24±1 hour at 37±0.5°C
3. 72±4 hours at 37±0.5°C

Hot Applications Samples:

1. 1 hour at 82±0.5°C
2. 1 hour at 82±0.5°C
3. 0.5 hour at 82±0.5°C + 72±4 hours at 37±0.5°C

Analyses are performed on final extractant water only. Water from first and second exposures is discarded. There is no time interval between exposures.

Pans: Cover 1,000 square inches (6451.6 cm^2) of surface area of samples received as shallow pans with 4 liters of "standard" water by pouring directly into the pan. Cover pan with sheet of glass during exposure.

Tanks: Tanks, including water softener and underground storage tanks shall be exposed as follows:

Calculate inside surface area of tank. Add sufficient volume of "standard" water to provide for exposure of entire tank inner surface at the ratio of 1 square inch (6.5 cm^2) to 4 ml water.

Place tank on its side for 72±4 hours at 37±0.5°C. Rotate tank one time each 24 hours to provide contact between water and entire surface area of tank to be exposed.

Discard water from first 72 hour exposure, refill with an equivalent volume of water and repeat entire exposure procedure.

Controls: Place equivalent volume of formulated water in extraction vessel and expose as a control. Include one control for each combination of extraction vessel and/or exposure condition in the daily sample run.

SECTION 4. RECOVERY OF WATER FOLLOWING EXPOSURE

4.0 SEPARATION: Separate water from exposed samples of plastics *immediately after exposure vessels are removed from*

elevated temperature environments by pouring through filter paper (white, crepe, VWR Grade 6.5) into ground glass stoppered bottles.

4.1 SAMPLE STORAGE: Remove plastics samples from exposure vessels, dry, return to properly marked storage bags and seal.

SECTION 5. TASTE AND ODOR EVALUATION

5.0 GENERAL REQUIREMENTS: Final extractant water exposed to plastics shall have a threshold odor number less than 40 for cold applications, and less than 60 for hot applications. A paired sample technique in which the stronger odor in each pair is identified shall be used in determining threshold odor levels.

5.1 PREPARATION: Odor-Free Water: Prepare odor-free water by passing distilled water through activated charcoal column.

Taste Test

Place 200 ml final extractant water (i.e., water from final exposure period) for each sample in separate BOD bottles. Place 200 ml control water in BOD bottle.

Odor Test

Cold Applications Samples:

Place 5 ml final extractant water in each of two BOD bottles and dilute to 200 ml with odor-free water.

Place 5 ml control water in each of two BOD bottles and dilute to 200 ml with odor-free water. (NOTE: Always prepare one bottle control water for each sample bottle. Odor is determined from duplicate sets of paired sample/control bottles prepared for each sample tested, as diagrammed in Figure A1.)

Retest all samples with threshold odor level of 40 or greater at 1:40 dilutions.

Hot Applications Samples:

Place 3 ml final extractant water in each of two BOD bottles and dilute to 200 ml with odor-free water.

Place 3 ml control water in each of two BOD bottles and dilute to 200 ml with odor-free water.

Retest all samples with threshold odor level of 60 or greater at 1:60 dilution.

Labelling: Label all bottles with three digit numbers selected from a table of random numbers. (NOTE: Odor evaluations can be performed at any threshold odor level of interest by diluting sample and control apropriately.)

5.2 TEST PROCEDURES: The NSF odor procedure is a modification of the paired sample technique described in American Society for Testing and Materials (ASTM) Special Technical Publiation 434: *Manual on Sensory Testing Methods,* prepared by ASTM Committee E-18. The modified procedure permits the panel member to identify the member of the sample/control pair containing the strongest odor versus identification of the control bottle in the pair. Statistical basis for the paired sample technique is appended.

Panel: Use panel of at least 10 members prescreened to eliminate persons who are unusually sensitive or insensitive to taste and odors.

Numbers of Samples: No less than two and no more than seven samples shall be evaluated at any time.

Taste Test:

Maintain all bottles - extractant water and control - at room temperature.

Arrange samples and control in random order for evaluation by panel.

Do not indicate to the panel which bottle contains control water.

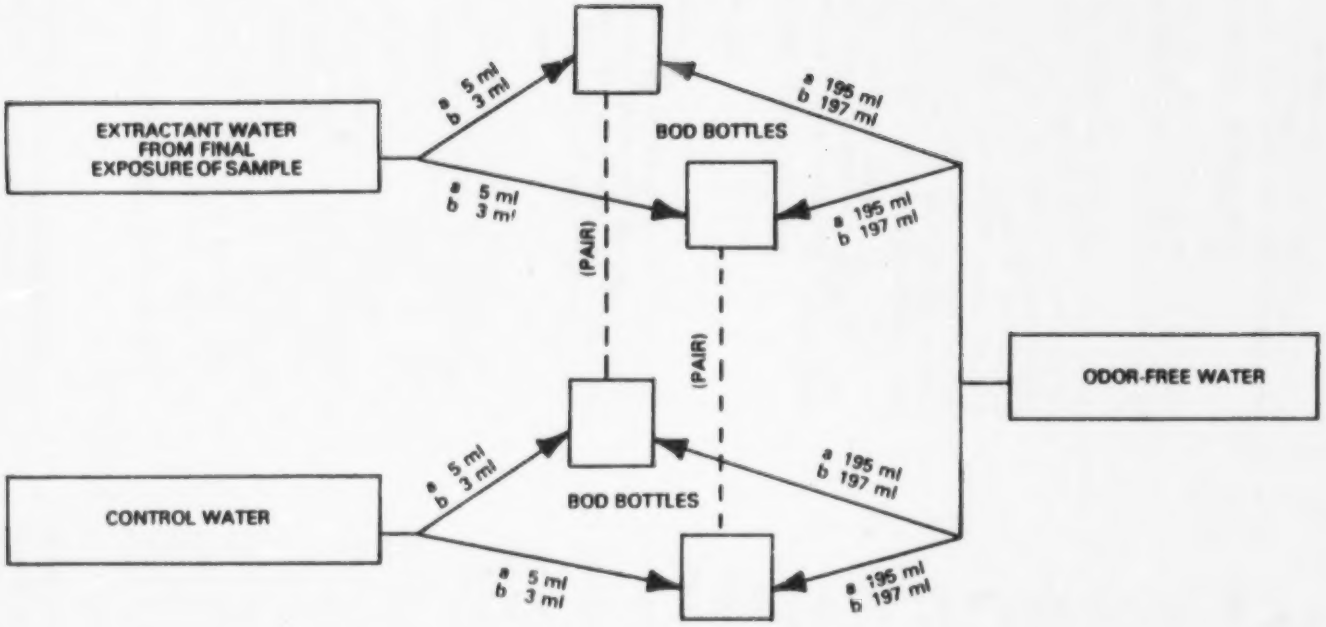
A panel member shall pour taste samples into 25 ml beaker and record taste as "sweet," "sour," "bittler" or "salty."

Panel member shall rinse mouth with odor-free water before proceeding to the next taste sample.

If panel consistently reports the taste of a particular sample to be more disagreeable than taste of the control, sample fails the taste test.

Odor Test:

Hold BOD bottles containing cold application samples and paired controls in water bath at 22°C. Hold hot application samples and paired controls in water bath at 60°C.



a = Threshold odor < 40 (1:40 dilution). All cold water applications samples.

b = Threshold odor < 60 (1:60 dilution). All hot water applications samples and retest of cold samples which fail 1:20 dilution; i.e., threshold odor ≥ 20.

Reproduced from best available copy.

Figure A1. Schematic Illustration of Preparation for Taste and Odor Evaluations

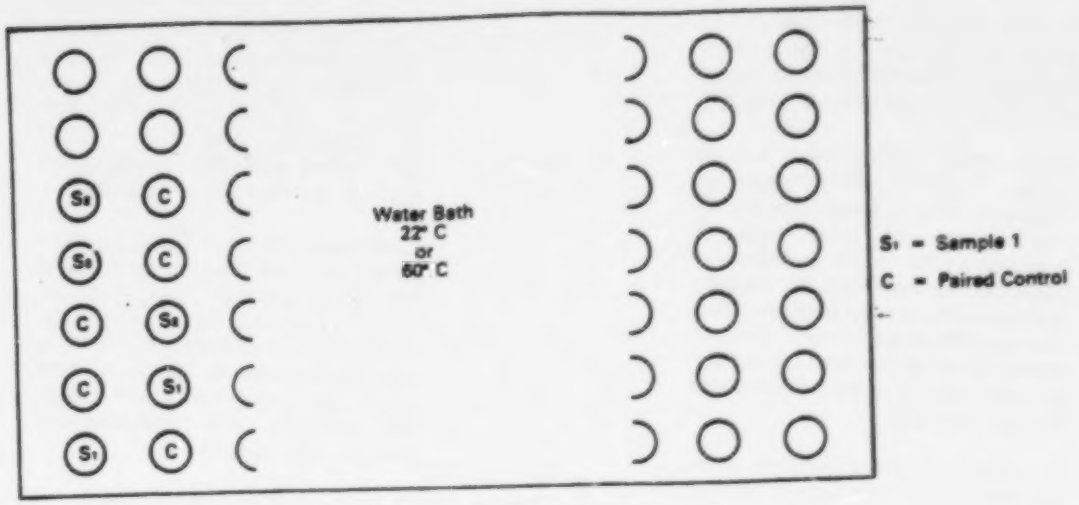


Figure A2. Water Bath Set-Up for Odor Test on Seven Samples

Arrange BOD bottles in water bath as shown in Figure A2. Include one bottle containing diluted extractant and one bottle with diluted paired control in each pair of bottles. Note that one S_1 bottle is placed left of C, the second S_1 bottle is right of C, but order of paired bottles is random.

A panel member shall examine each pair in turn and determine which member of the pair has the strongest odor.

Data from all panel members are summed and reported as the number of times sample was selected as the member of the pair which contained the strongest odor. Table A-III is used to determine whether sample passes or fails, based on the number of times sample was presented for analysis; e.g., 2n, where n = number of panel members.

5.3 GENERAL DISCUSSION OF ODOR TEST PROCEDURES: References are to ASTM Special Technical Publication 434: *Manual on Sensory Testing Methods,* sponsored by ASTM Committee E-18 on Sensory Evaluation of Materials and Products.

5.3.1 It is impossible to achieve statistically significant results with fewer than three panel members under test conditions specified. With five panel members, more than one error would make the result insignificant at the 95 percent confidence level. With 10 panel members, a 15 percent error rate will still allow results significant at the 99 percent confidence level. If it is necessary to use a different number of panel members, the criterion for failing must be appropriately adjusted (see IV.E.4.d.[1] and NSF Standard 14, Table I).

Panel members should have the test procedures carefully explaind to them. Specifically, they should understand that they must choose which bottle in a pair has the strongest odor regardless of how confident they are in their selection. Clearly, if the difference between the control and the sample is quite noticeable, nobody should make any errors. If the difference is unnoticeable, then overall there is a 50-50 chance of making an error. The significance of the test occurs when the panel as a whole is closer to 100 percent right than 50 percent right, and this depends on each panel member making his/her best judgement on each pair. The panel members should be reminded that the order of samples in the test is completely

[1]Reference ASTM Special Technical Publication 434: *Manual on Sensory Testing Methods,* sponsored by ASTM Committee E-18 on Sensory Evaluation of Materials and Products.

random and that in every pair, one bottle is identical to the control bottle and the other bottle contains sample extractant (see I.B.3.A.[1][1]).

5.3.2 Two sample bottles are prepared for each sample to control for "position error" (see Item 5.3.6), and to have 20 rather than 10 evaluations for each sample, increasing the likelihood for statistically significant results when there is a real difference in odor. This requires 1[illegible] ml of the sample extractant and 390 ml of odor-free water for each sample.

5.3.3 If n is the number of samples to be run (not more than seven), the 2n control bottles must be prepared. Maximum total requirement is 270 ml of control water. Maximum total requirement of odor-free water is 6.0 liters (including odor-free water used in sample bottles).

5.3.4 Reference I.B.6.e.[1]

5.3.5 The key sheet is clearly needed for control and records. The key sheet should include date and time of testing and adequate information to identify later the samples being tested.

5.3.6 Each sample must occur once on the left in a pair and once on the right in a pair to control for position error (reference I.C.3.e.[3])[1]. The sequence in which the pairs are placed must be random to reduce the likelihood of error based on order of presentation. The panel members must be informed that the sequence, in fact, is random.

5.3.7 The panel member's response sheet should include identification of the panel member, and the date and time of testing. Spaces should be provided to record either "left" or "right" for each pair in the test and the pair number.

5.3.8 Reference I.C.3.f.(4)(d)[1]

5.3.9 The confidence levels given in Table A-IV are described as 1-p, where p is the probability of getting at least the specified number of correct identifications of the control, given that the control is identical to the sample (e.g., 99 percent confidence level means that 1 percent of the time, at least the specified number is expected when there is no difference in the odor of the sample and control).

Confidence levels in Table A-IV are obtained from the percentiles of the "t" distribution. This distribution is parameterized by the sampling degrees of freedom. The degree of freedom is 19 for the test procedure using ten panel members and two pairs containing the sample and control.

The t-value is computed by the formula:

$$t = \frac{F - 0.5}{\sqrt{\frac{.5 \times .5}{19}}} = \sqrt{19}\ (2F - 1)$$

where F = the fraction of correct choices, t can be evaluated for different numbers of correct identifications of the control:

Number Correct	t-value	Confidence Level (%)[1]
14	1.74	90.0
15	2.18	97.5
16	2.62	98.0
17	3.05	99.50
18	3.49	99.50
19	3.92	99.95

[1]These are the entries for No. responses equal to 20 in Table A-IV; the other entries in Table A-IV were obtained in a like manner.

SECTION 6. CHEMICAL METHODS

6.0 HEAVY METALS

6.0.1 GENERAL: The determination of heavy metals in extractant water is accomplished, with the exception of chromium, using atomic absorption analysis. This technique is based on the quantum mechanical principle that atoms absorb light at energy levels corresponding to characteristic orbital energies of the atom. By measuring the attenuation of a monochromatic

TABLE A-IV

CONFIDENCE LEVELS[1]

No.[2]	No. of responses														
	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48
10	N.S.[3]														
11	N.S.	N.S.													
12	75.00	60.00	N.S.												
13	90.00	75.00	60.00	N.S.											
14	95.00	75.00	75.00	60.00	N.S.										
15	97.50	90.00	75.00	75.00	60.00	N.S.									
16	98.00	97.50	90.00	75.00	75.00	60.0	N.S.								
17	99.50	98.00	95.00	90.00	75.00	75.00	60.00	N.S.							
18	99.50	99.50	97.50	95.00	90.00	75.00	75.00	N.S.	N.S.						
19	99.95	99.50	99.50	97.50	95.00	90.00	75.00	75.00	60.00	N.S.					
20	99.95	99.95	99.50	99.00	99.00	95.00	90.00	75.00	60.00	60.00	N.S.				
21		99.95	99.50	99.50	99.00	97.50	95.00	90.00	75.00	60.00	60.00	N.S.			
22		99.95	99.95	99.50	99.50	99.00	97.50	95.00	90.00	75.00	60.00	60.00	N.S.		
23			99.95	99.95	99.50	99.50	97.50	97.50	95.00	75.00	75.00	60.00	60.00	N.S.	
24			99.95	99.95	99.95	99.50	99.00	97.50	97.50	90.00	75.00	75.00	60.00	60.00	N.S.
25				99.95	99.95	99.95	99.95	99.00	97.50	95.00	90.00	90.00	75.00	60.00	60.00
26				99.95	99.95	99.95	99.95	99.50	99.00	97.50	95.00	90.00	75.00	75.00	60.00
27					99.95	99.95	99.95	99.50	99.50	99.00	97.50	95.00	90.00	75.00	75.00
28					99.95	99.95	99.95	99.95	99.95	99.50	99.00	97.50	95.00	90.00	75.00
29						99.95	99.95	99.95	99.95	99.50	99.50	99.00	97.50	95.00	90.00
30						99.95	99.95	99.95	99.95	99.50	99.50	99.50	97.50	97.50	95.00
31							99.95	99.95	99.95	99.95	99.50	99.50	99.50	97.50	97.50
32							99.95	99.95	99.95	99.95	99.95	99.50	99.50	99.00	97.50
33								99.95	99.95	99.95	99.95	99.95	99.50	99.50	99.00
34								99.95	99.95	99.95	99.95	99.95	99.95	99.50	99.50
35									99.95	99.95	99.95	99.95	99.95	99.50	99.50
36									99.95	99.95	99.95	99.95	99.95	99.95	99.50

[1]Sample fails when confidence level reaches 99% or greater

[2]Number of times sample identified as strongest odor in sample/control pair.

[3]N.S. = No significant difference.

light beam passing through the sample atoms, the concentration of metal in the sample can be determined using Beer's Law.

NSF employs an external standard technique for calibration and sample determination. Three standard solutions are made in concentrations corresponding to the region in which the samples are expected to lie. Standards are run concurrently with samples to insure quality control and to indicate any significant deviations in instrumental response. The concentrations of the samples are then obtained from graphs of absorbance versus concentration for the standards.

A study of testing results for several routine analyses was made to determine reproducibility and levels of detection obtained on average working days in the NSF laboratories. This study was done without the prior knowledge of laboratory personnel.

Detection limits were determined as twice the noise level of the recorder output for an analysis. Reproducibility was detemined to be the standard deviation of the absorbance values obtained for a specific concentration of a standard. Arithmetic mean values of the standard were then plotted against concentration, and a least squares line drawn. Detection limits and reproducibility values were then determined from this graph. This procedure was followed for each metal. The results are shown in Table A-V.

Updating analytical procedures is a continuous process at NSF.

All standards and samples are made in the matrix of NSF formulated extractant water[2].

6.0.2 EQUIPMENT:

Perkin-Elmer Model No. 560 atomic absorption spectrophotometer

TABLE A-V

DETECTION LIMITS AND REPRODUCIBILITY OF METALS ANALYSES

Metal	MCL[1] (mg/l)	Reproducibility at MCL (mg/l)	DL[2] (mg/l)	Reproducibility at lowest standard (mg/l)
Antimony	0.05	±0.0007	0.007	±0.0005
Arsenic	0.05	±0.0007	0.004	±0.0008
Barium	1.0	±0.05	0.008	±0.004
Cadmium	0.01	±0.0002	0.0005	±0.0001
Chromium	0.05	±0.002	0.005	±0.002
Lead	0.05	±0.0009	0.002	±0.0007
Mercury	0.002	±0.0004	0.0003	±0.0004
Selenium	0.01	±0.001	0.003	±0.0005
Tin	0.05	±0.002	0.005	±0.0009

[1]maximum contaminant limit (MCL)

[2]detection limit (DL)

[2]NSF Standard No. 14, Appendix A, Section 2.

E.D.L. Power Supply, P.E. No. 040-0354

Perkin-Elmer Graphite Furnace, H.G.A. 2200

Perkin-Elmer PRS-10 Printer Sequencer

Perkin-Elmer AS-1 Auto Sampling System

Burner Control Box, P.E. No. 057-0262

Perkin-Elmer Hitachi 200 Recorder

Acetylene Gas Tank and Regulator

Argon Gas Tank and Regulator

Nitrous Oxide Gas Tank and Regulator

Inorganic 1000 ppm metal standards in matrix of dilute hydrochloric acid

Eppendorf micro-pipets

6.0.3 PROCEDURE, (Atomic Absorption Spectrophotometer) AAS:

Atomization Method - graphite furnace (except mercury)

Sample Matrix - 0.1 ml of Suprapur® HNO_3 in 50 ml of extractant water

Slit - Alternate

Gain — Set between 35 - 40 units

Source — Set to specifications of lamp being used

Signal — Absorbance

Mode — Continuous

Recorder - Absorbance

Background Corrector - AA (Background correction not used routinely)

Recorder Chart Expansion - Set as desired

The lamp is allowed its specified warm up time

Standards are made by adding appropriate aliquots of 1000 ppm standards to the correct matrix. Controls are made with the same matrix but with no exposure to plastics and no addition of the standard.

After proper alignment, each standard is analyzed at least two times. Following this, controls and samples are analyzed two times. Standards are interspersed in the analysis with a total standard frequency of no less than 5 percent of analysis time. Following the completion of the sample run, each standard is rerun. If the instrument response has changed, all questionable samples are rerun immediately followed by a series of standards.

6.0.4 METHODS:

Antimony (Sb):

Standards — 0.1, 0.05, 0.02 mg/l

Graphite Furnace Settings

	Temperature °C	*Time,* Sec.
Dry	110	20
Char	825	22
Atomization	2700	6

Purge gas - Argon
Purge gas flow rate - 300 cc/min
Purge gas interrupt — 3 sec.
Sample volume 20 2µl

Instrumental Parameters

- Slit — 0.2 mm
- Source — HCL, P.E. No. 303-6010
- Wave length — 217.6 nm

Photometric Range - 0.5

Arsenic (As):

Standards — 0.100, 0.050, 0.020 mg/l

Graphite Furnace Settings

	Temperature °C	*Time, Sec.*
Dry	110	20
Char	250	20
Atomization	2700	6

Purge gas - Argon
Purge gas flow rate - 300 cc/min
Purge gas interrupt — 3 sec.
Sample volume 20 µl

Instrumental Parameters

- Slit — 0.7
- Source — EDL, P.E. No. 303-6211
- Wave length — 193.7 nm

Photometric Range - 0.5

Barium (Ba):

Standards — 0.100, 0.050, 0.020 mg/l

Graphite Furnace Settings

	Temperature °C	*Time, Sec.*
Dry	110	23
Char	1100	36
Atomization	2700	5

Purge gas - Argon
Purge gas flow rate - 300 cc/min
Purge gas flow reduction rate - 110 cc/min for 3 sec.
Sample volume — 20 µl

Instrumental Parameters

- Slit — 0.2
- Source — HCL, P.E. No. 303-6012
- Wave length — 553.6 nm

Photometric Range - 0.5

Cadmium (Cd):

Standards - 0.0100, 0.0050 0.0020 mg/l

Graphite Furnace Settings

	Temperature °C	Time, Sec.
Dry	110	20
Char	280	32
Atomization	2100	6

Purge gas - Argon
Purge gas flow rate - 300 cc/min
Purge gas interrupt - 3 sec.
Sample volume - 20 µl

Instrumental Parameters

- Slit - 0.2
- Source - HCL, P.E. 303 .601b
- Wave length - 228.8 nm

Photometric Range - 1.0

Chromium (Cr):

Standards - 0.100, 0.050 0.020 mg/l

Graphite Furnace Settings

	Temperature °C	Time, Sec.
Dry	110	20
Char	1100	32
Atomization	2700	6

Purge gas - Argon
Purge gas flow rate - 300 cc/min
Purge gas interrupt - 3 sec.
Sample volume - 20 µl

Instrumental Parameters

- Slit - 0.7
- Source - HCL, P.E. 303-6021
- Wave length - 357.9 nm

Photometric Range - 1.0

Lead (Pb):

Standards - 0.050, 0.030, 0.010 mg/l

Graphite Furnace Settings

	Temperature °C	*Time, Sec.*
Dry	110	20
Char	700	20
Atomization	2300	6

Purge gas - Argon
Purge gas flow rate - 300 cc/min
Purge gas interrupt - 3 sec.
Sample volume - 20 µl

Instrumental Parameters

•Slit - 0.7
•Souce - HCL, P.E. 303-6111
•Wave length - 217.0 nm

Photometric Range - 0.2

Mercury (Hg):

Sample Matrix - sample water treated in accordance with Perkin-Elmer instructions for Mercury Analysis System No. 303-0830

Standards - 0.010, 0.0050, 0.0020 mg/l

Atomization Method - Perkin-Elmer Flameless Mercury Analysis System 303-0830

Instrumental Parameters

•Slit - 0.7
•Souce - HCL, P.E. 303-6044
•Wave length - 253.7 nm

Photometric Range - 0.5

Selenium (Se):

Standards - 0.050, 0.020, 0.0050 mg/l

Graphite Furnace Settings

	Temperature, °C	*Time, Sec.*
Dry	110	20
Char	370	36
Atomization	2700	5

Purge gas - Argon
Purge gas flow rate - 300 cc/min
Purge gas interrupt - 3 sec.
Sample volume - 20 µl

Instrumental Parameters

•Slit - 0.7
•Source - EDL, P.E. 303-6262
•Wave length - 196.0 nm

Photometric Range - 0.2

Tin (Sn):

Standards - 0.100, 0.050, 0.020 mg/l

Graphite Furnace Settings

	Temperature °C	*Time Sec.*
Dry	110	30
Char	700	32
Atomization	2700	5

Purge gas - Argon
Purge gas flow rate - 300 cc/min
Purge gas interrupt - 3 sec
Sample volume - 20 µl

Instrumental Psameters

•Slit - 0.7
•Source - EDL, P.E. 303-6274
•Wave length - 224.6 nm

Photometric Range - 0.5

6.0.5 QUALITY CONTROL: Any plastics sample which fails any chemical parameter is retested to assure that the problem is associated with the sample versus the analysis or analytical technique.

In accordance with the 14th Edition of *Standard Methods for the Examination of Water and Wastewater,* the NSF laboratory utilizes two methods of quality control, internal and external. The internal method includes standard solutions and controls which correct for chemical interference in the extractant water. Standards and controls comprise 15% of the analytical time for heavy metals determinations; i.e., one in six randomly spaced controls.

External quality control samples are analyzed on an average of once every three months, either as EPA reference standards or solutions of NSF extractant water spiked with metals at concentrations which approximate a "typical" plastics sample. The quality control samples are prepared by personnel

other than those involved in the analysis and are coded in a manner which simulates actual plastics samples. The analyst receives the quality control sample, along with actual plastics samples, with no knowledge of its status as a quality control sample.

6.1 RESIDUAL VINYL CHLORIDE MONOMER (RVCM)

6.1.1 GENERAL: It has been demonstrated that a level of 10 ppm RVCM in PVC and CPVC piping system components will result in undetectable (where detection is 50 ppb) levels of RVCM leaching into water passing through the system. Accurate determination of these low levels of RVCM is made using gas chromatographic (GC) separation and flame ionization detection.

A small amount of plastic is dissolved in a sealed tube half filled with an appropriate solvent. The tubes are then heated so that essentially all the vinyl chloride monomer (VCM) goes into the vapor phase (head space). An aliquot of head space is then injected into the GC system and analyzed for VCM content.

For the first six months that NSF tested for RVCM content in accordance with Standard No. 14 using this procedure, two independent laboratories participated with NSF in round-robin testing. In the 0 to 20 ppm range, the average variation about mean values of duplicate samples was less than 1 ppm. For samples exchanged which were found to have greater than 20 ppm RVCM, the average deviation was ± 4.1 percent. To date, the average deviations (reproducibilities) of standard solutions used by NSF have been less than 0.2 ppm. These standards contained 10-20 ppm of VCM.

6.1.2 EQUIPMENT: (All equipment and parts numbers through the Septa-Sandwich Type refer to Perkin-Elmer designations)

Gas Chromatograph, Perkin-Elmer Model F-42 Head Space Analyzer, No. 105003

Flame Ionization Detector (F.I.D.) No. 1050201 (sensitivity .015 coul/gC)

Model I Computing Integrator, No. 023-1001

Columns — ⅛" x 3' and ⅛" x 6' Carbowax 1500, No. 1050254

Back Flush Unit, No. 1050224

Thermometer 0°-100°C, No. 105-0109

Sample Tray Thermostat System (Haake), No. 1050124

Sample Bottles, No. 1050118

Septa-Sandwich Type, for Automatic Dosing, No. 105-1008

Hydrogen Cylinder with Regulator and Filter Drier

Air Cylinder with Regulator and Filter Drier

Nitrogen Cylinder with Regulator and Filter Drier

Analytical Balance, capable of weighing ± .0001 g

Soap Film Flow Meter, Hewlett Packard, No. 0101-113

Pressure-Lok Series A-2 Syringe, 0-100 microliter

10 Microliter Liquid Syringe

Repipet, with 1000 ml square amber bottle and 20 ml pipet, Fisher No. 13-687-36

Thomas-Atlab Reciprocating Shaker, No. 8289-B10

6.1.3 REAGENTS:

Vinyl Chloride (VC) — 99.9 percent (if available)

N,N-Dimethylacetamide (DMAC), redistilled in glass

6.1.4 INSTRUMENT PREPARATION:

Install three foot (0.9 m) column between the injector and the backflush tee; connect six foot (1.8 m) column to the backflush tee. Do not connect the six foot (1.8 m) column to the detector until the column has been conditioned.

Neumatic Settings:

- Nitrogen
- Tank regulator, 40 psi (275.8 kPa)
- Chromatograph regulator at 1.0 Bar

These settings yield a resultant flow of 240 ml/min with the columns used and optimize interference separation and analytical speed. The retention time is 70 seconds.

Hydrogen

- Tank regulator, 42 psi (289.5 kPa)
- Chromatograph regulator, 2.1 Bar

Air

- Tank regulator, 40 psi (275.8 kPa)
- Chromatograph regulator, 2.5 Bar

F.I.D.

- Air and Hydrogen, 2.5 Bar

NOTE: The air-hydrogen mixture is adjusted to maximize detector response.

Backflush

- Backflush regulator, 1 Bar

Temperature settings

- Oven — 80° C
- Needle — 150° C
- Injector and detector — 150° C
- Water bath — 90° C

Program Settings

- Injection time — 4 sec.
- Analysis time — 1 min.
- Backflush time — 3 min.
- Waiting time — 0.3 min.

NOTE: The program settings are functions of column characteristics (i.e., length, packing, retention, etc.) and may need to be changed when columns are changed or reconditioned.

6.1.5 ANALYTICAL PROCEDURE:

Prior to sample analysis, prepare standards containing 300 to 700 ppm of VCM, to be used for column conditioning.

Standard Stock Preparation

- Standard stock solutions are prepared monthly. A small portion of liquid VCM (approximately 30 μl) is injected into a sealed sample bottle filled with DMAC. The sample bottle and DMAC are preweighed so that the weight of DMAC is known. The difference between the final weight and the weight of the bottle and DMAC is the weight of VCM added. This weight can be used to determine the concentration of VCM in the DMAC. These stock standards can be refrigerated and stored for more than six months.

- Example

D $\frac{25}{4}$ DMAC = 0.9366 g/ml

D $\frac{25}{4}$ VCM = 0.9080 g/ml

(0.0272 g VCM) / (0.9080 g/ml VCM) = 0.03 ml VCM

(22.4782 g DMAC) / (0.9366 g/ml DMAC) = 23.9998 ml DMAC

Standard Stock = (0.0272 g VCM) / (23.9998 ml DMAC + 0.03 ml VCM) = 0.0011 g/ml VCM

Calibration Standard Preparation

- Add 10 ml of DMAC to a sample vial and seal

- Inject an appropriate amount (10 μl) of stock solution under the surface of the DMAC

- Calculate the weight of VCM in

the sample bottle as follows: (0.0011 g/ml) (0.010 ml) = 0.000011 g VCM

•Convert to ppm with respect to a 0.5000 g sample as follows:

$$\frac{(1.1 \times 10^{-5}\ g)\ (1 \times 10^{6})}{0.5000\ g} = 22\ ppm$$

NSF standards are normally in the 10 to 30 ppm range.

Sample Preparation

•Take sample shavings from various locations around the perimeter of the sample to be tested. This minimizes the heat generated by taking shavings and gives a representative cross-section of the pipe or fitting.

•Add 0.5 g (to the nearest 0.1 mg) of sample to a sample bottle.

•Add 10 ml of DMAC to sample vial and seal vial.

•Shake sample vials until plastic is completely dissolved.

(NOTE: Small particles, additives, are sometimes observed; these will not affect the analysis.)

•Load the carousel with three "wake-up" bottles (if this is the first run of the day), three standards for calibration, and the samples interspersed with an occasional standard (15 percent of analyses are standards and/or blanks).

6.1.6 QUALITY CONTROL: Analyze all samples in duplicate. If the mean result of the duplicate is greater than the maximum permissible limit, analyze a new sample in duplicate. If it should fail this second test, the manufacturer is requested to submit additional pipe and the same sequence is repeated. Consequently, a sample is reported as failing only after four duplicate analyses.

In addition to the daily standard solutions which are interspersed with the samples, standard stock solutions from previous days are included routinely.

6.2 OTHER CHEMICAL PARAMETERS

6.2.1 PHENOLS: Phenols are measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, 14th Edition, page 577 (4-aminoantipyrine method with preliminary distillation step).

6.2.2 ACRYLONITRILE: Acrylonitrile is measured in accordance with ASTM D1013.

6.2.3 SOLIDS, TOTAL (DISSOLVED): Total dissolved solids are measured in accordance with *Standard Methods for the Examination of Water and Wastewater,* 14th Edition, page 91.

6.3 TOTAL TRIHALOMETHANE (TTHM) ANALYSIS — IN-THE-PIPE EXPOSURE:

6.3.1 GENERAL: EPA has set the maximum total trihalomethane (TTHM) level in drinking water at 100 ppb (μg/l).[3] Levels of individual trihalomethanes, (THMs) leached from CPVC and PVC pipe into water are determined by gas chromatography (GC) after exposing the pipe to a standard extractant water. Five other organohalides (1,2-Dichloroethane, 1,1,1-Trichloroethane, Carbon Tetrachloride, Trichloroethylene, and Tetrachloroethylene) are monitored along with the THMs. If a sample chromatogram shows a peak at a retention time not corresponding to one of the nine compounds to be specifically analyzed, that peak is identified by gas chromatography/mass spectrometry (GC/MS), quantitated, and reported.

[3]Federal Register, Vol. 44, No. 231, November 29, 1979, including Part III, Appendix C.

A pipe is filled with extractant water, stoppered, and exposed according to NSF's standard (multiple) cold exposure procedure. The pipe surface area to water volume ratio is calculated according to the inside diameter (ID) of the exposed pipe. The exposure water is then injected into a purge and trap liquid concentrator linked to a GC system, for TTHM analysis.

6.3.2 EQUIPMENT:

Gas Chromatograph, Tracor 565

Computing Integrator, Spectra Physics SP4100

Purge and trap liquid concentrator, Tekmar LSC-2 with autosampler, Tekmar Model ALS Automatic Laboratory Sampler

Columns
- GC - 2 mm ID x 2 m glass column packed with 1 percent SP-1000 on 60/80 mesh Carbopack B
- Purge and Trap - Tenax/Silica Gel Trap

Detector - Hall Electrolytic Conductivity Detector, Tracor 700A

Helium cylinder (Grade 5) with 2-stage regulator and oxygen trap

Hydrogen cylinder (Grade 5) with 2-stage regulator and activated carbon filter

Analytical balance, capable of weighing ±0.0001 g

Soap film flow meter, Hewlett Packard No. 0101-113

25 ml volumetric flask, screw cap with Teflon®-faced silicone septum

100 ml volumetric flask, screw cap with Teflon®-faced silicone septum

Syringes
- 5 ml glass with luer lock tip
- 25μl Hamilton micro syringe 702N; Syringe valve

Sampling vials, Pierce 13075 40 ml screw cap vials with Pierce 12722 Teflon®/Silicone Closures

Teflon® or ground glass tapered closures to fit a variety of pipe diameters

6.3.3 REAGENTS:

Organic-free water, Millipore Milli-Q® water system with Organex-Q® cartridge

n-Propanol

Methanol

Reference Material[4]
- Bromoform 97 percent
- Bromodichloromethane 98 percent
- Carbon Tetrachloride 98 percent
- Chlorodibromomethane 98 percent
- Chloroform 99 percent
- 1,2-Dichloroethane 97 percent
- Tetrachloroethylene 98 percent
- 1,1,1-Trichloroethane 98 percent
- Trichloroethylene 98 percent

6.3.4 INSTRUMENT SETTINGS: Install the prepared and conditioned (at 220°C overnight with a carrier gas flow of 40 ml/min.) GC column listed above according to manufacturer's instructions. Optimize reactor temperature of Hall detector according to manufacturer's instructions. Set output level to 1000 to accommodate negative peaks, SP4100 as needed.

Pneumatic Settings:
- Helium: 25 ml/min.
- Hydrogen: 50 ml/min.

Program Settings:
- GC Oven
  Initial temperature - 25°C
  Initial hold time - 1 min.
  Ramp rate - 8°/min
  Final temperature - 215°C
  Final hold time - 10 min.

[4]All reference material may be obtained from Aldrich Chemical Co.

•Purge and Trap
Purge gas - Helium
Purge flow - 40 cc/min.
Purge time - 12.0 min.
Purge temperature <30°C
Desorb time - 4.0 min.
Desorb temperature - 180°C
Bake time - 8.0 min.
Bake temperature - 180°C

6.3.5 PROCEDURES FOR SAMPLE PREPARATION AND EXTRACTANT WATER EXPOSURE:

Samples

Requirements: Pipe ID must be 2 inches (50.8 mm) or less; this procedure is not intended for pipes larger than 2 inches (50.8 mm) ID. The surface area to water volume ratio of the exposure may be calculated using the following formula:

$$\text{ID of pipe sample (in.)} \times 9.766 = \text{Surface area/Vol. ratio } (\text{in.}^2/\text{ml})$$

Preparation: Cut pipes to a length that will hold a minimum of 50 ml of exposure water. Cut ends flush, deburr,and trim to accommodate closures.

Washing: Hand wash prepared samples with detergent, brushing the inside of the pipe lightly. Rinse with tap water, rinse with organic-free water, and allow to air dry in an uncontaminated atmosphere.

Extractant Water

Chemical Characteristics: Prepare "standard" extractant water to contain 100 mg/l hardness (as $CaCO_3$) in organic-free water.

Reagents: Buffer Stock Solution: Dissolve 3.36 g Sodium Bicarbonate ($NaHCO_3$) in organic-free water. Make up to one liter.

Hardne ; Stock Solution: Dissolve 4.44 g anhydrous Calcium Chloride ($CaCl_2$) in organic-free water. Make up to one liter.

Water: Prepare extractant water by adding stock reagent solutions to organic-free water, as shown in Table A-VI.

TABLE A-VI
EXTRACTANT WATER

Organic-Free Water (Liters)	Buffer Stock Solution (ml)	Hardness Stock Solution (ml)
1	25	25
6	150	150
12	300	300
15	375	375

Exposure

Pipe Closures: Stopper one end of pipe sample using standard taper ground glass stoppers or tapered Teflon® plugs (whichever is available to accommodate ID of pipe sample). Fill pipe to overflowing with extractant water. Tap sides of the pipe to release any air bubbles and insert a stopper in the other end of the pipe, being careful to avoid the formation of headspace. Check ends for leaks.

Exposure Conditions: All tests for acceptance, qualification, and routine monitoring are conducted with a multiple exposure procedure. Analysis is performed on the final extractant water only.

Multiple Exposures:
1. 24± 1 hour at 37±0.5°C
2. 24± 1 hour at 37±0.5°C
3. 72± 4 hours at 37±0.5°C

Controls: Fill a 40 ml glass vial, having a screw cap and Teflon®-lined silicone septum, with extractant water. Expose along with pipe samples during the final exposure (72±4 hours at 37±0.5°C). Include at least one control for every 10 pipe samples in the daily run.

Recovery of Water Following Exposure

Pouring: Observe the pipe, check for and note any signs of leaks or headspace. Remove the stopper from one end of the pipe sample and pour the water into a clean 40 ml screw cap vial (washed in dishwasher, rinsed in Milli-Q,® baked at 105°C for 1 hour, and allowed to cool to room temperature in an uncontaminated atmosphere) to overflowing. Seal the vial without headspace using a Teflon®-lined silicone septum.

Sample Water Storage: Store the sealed sample vials at 4±0.5°C until time of analysis. The storage time may not exceed 14 days. Samples must be brought to room temperature before analysis.

6.3.6 ANALYTICAL PROCEDURE:[3] Prior to analysis, GC conditions and requirements must be met before analysis may continue.

Standardization and Calibration

Standard Stock Preparation: Prepare standard stock solutions monthly. Place about 24 ml of methanol in a 25 ml volumetric flask. Weigh the flask to the nearest 0.1 mg. Drop 2 to 3 drops of reference standard directly into the methanol. Reweigh the flask to determine amount of reference standard added. Dilute to volume and mix by inverting several times. Transfer the standard stock solution into a 15 ml screw cap bottle with a Teflon® liner. Store at 4°C. Standard may be used for up to 4 weeks of daily check standards if documentation shows no significant changes in peak areas.

Aqueous Calibration Standard: Rapidly inject a measured amount of the stock solution, using a 25µl Hamilton 702N microsyringe, into the expanded area of a volumetric flask (no more than 20µl into 100 ml of organic-free water) filled with organic-free water. Mix by inverting the flask three times. Discard aqueous standards after one hour unless stored as described in Section 6.3.5, Recovery of Water Following Exposure, in this procedure.

Quality Check Standard: Before sample analysis, run a 2 mg/l quality check standard. Analysis of this standard must result in concentrations within 20 percent of the true values.

Analytical Quality Control

Instrument Status and Lower Limit of Detection (LOD): Determine daily the LOD of each compound based on the Quality Check Standard and the noise level of the base line, as follows:.

$$\text{LOD } (\mu g/l) = \left(\frac{A \times ATT}{B \times ATT}\right) C$$

B50
9

A = 5 times noise level (mm) at exact retention time of the THM

B = Peak height (mm) of Quality Check Standard

C = Concentration (mg/l) of Quality Check Standard

ATT = Attenuation factor

Sample Blank: Analyze daily organic-free water for potential interferences.

Generated Spike: Every tenth sample, analyze a laboratory-generated spike of organic-free water made at the time of analysis.

Duplicate Analysis: Analyze 10 percent of all pipe samples in duplicate.

Exposure Spike: Expose duplicate lengths of 10 percent of all samples as in Section 6.3.5 using exposure water spiked with each of the nine organic compounds to a concentration of 5 - 10 µg/l, as opposed to organic-free water.

Precision and Accuracy: Maintain records of precision and accuracy data collected from Quality Check Standards, duplicate analyses, generated spikes, and exposure spikes.

Retention Times: Maintain a record of retention time for each reference standard. Retention times may not vary by more than 10 percent of the established norm.

Analysis

Sampling: Pour sample to be analyzed into a clean 5 ml syringe with a luer lock tip and 2-way valve. Load 5 ml of sample into purge and trap device.

Parameters: Set Purge and Trap and GC conditions as stated in Section 6.3.4 and start analysis.

Calculations: Identify each compound in the resulting chromatogram by comparing retention times of sample peaks to retention times of reference peaks from Quality Check Standard.

Calculate the concentration of sample peak by comparing peak area of sample to the peak area and concentration of the reference standard peak. Report results to two significant figures.

6.3.7 ALTERNATE METHOD OF ANALYSIS: When the Purge and Trap method of sample extraction cannot be employed, an alternative method is available. The alternative method involves a liquid/liquid sample extraction.[3] Major drawbacks to the method are that 1,2-dichloroethane cannot be detected, and the maximum detectable amount of carbon tetrachloride is about 15 µg/l due to detector saturation.